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(71) Applicant and

(72) Inventor (for all designated States except US): **PERRI-
CONE, Nicholas, V.** [US/US]; Clinical Creations, 377 Re-
search Parkway, Meriden, CT 06450 (US).

(74) Agent: **KRINSKY, Mary, M.**; 79 Trumbull Street, New
Haven, CT 06511-3708 (US).

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(54) Title: SKIN TREATMENTS USING BLUE AND VIOLET LIGHT

(57) Abstract: Aging or damaged skin is treated by irradiating affected skin areas with an effective amount of blue and/or violet visible light having a wavelength of about 400 nm to about 500 nm. The light may be sunlight or artificial light, coherent or non-coherent, pulsed or continuous, of high or low energy, exposed generally or directed to target areas, or any combination of these. A variety of irradiation methods may be employed. In one embodiment, filtered sun or artificial light is used. This can be widely exposed to skin areas, or directed to discrete skin regions, particularly to areas especially susceptible to aging, e.g., the backs of hands and the periorbital and perioral areas of the face. In an alternate embodiment, light-emitting diodes are applied directly to discrete skin areas as needed as patches or thin sheets such as pliable masks. Green light (about 500 to about 590 nm) may be used as adjunct therapy with blue/violet light in some embodiments. Compositions containing compounds that enhance light penetration of the stratum corneum such as α -hydroxy acids (e.g., glycolic acid) and/or filter light may be applied to the skin prior to or during phototreatment.



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SKIN TREATMENTS USING BLUE AND VIOLET LIGHT

BACKGROUND OF THE INVENTION

Field of the Invention. This invention relates to the treatment of damaged and aging skin with light therapy, including both clinical and cosmetic phototreatments.

5 Description of Related Art. Skin inflammation and aging are closely related phenomena. So similar are the processes involved with both, that aging is sometimes described dermatologically as a chronic low grade inflammatory condition. Both inflammation and aging are initiated in part by free radical damage, which takes place mostly within the cell membrane. The cell membrane
10 is most susceptible to attack by free radicals because of its higher oxygen tension in comparison with the cytosol and its dense molecular structure largely comprising lipids and lipoproteins, which are easily oxidized by reactive oxygen species such as singlet oxygen, the superoxide anion, and hydroxyl radicals. These and other free radicals are generated in normal metabolism, as well as through
15 ultraviolet sun exposure, exposure to other forms of ionizing and non-ionizing radiation, environmental factors such as pollution or exposure to chemicals in the home or workplace, and stresses such as infection or extreme exercise. The body's endogenous antioxidant defense systems made up of antioxidants such as vitamins C and E, glutathione, and enzymes, *e.g.*, superoxide dismutase, are over-
20 whelmed.

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In the body's response, proinflammatory and inflammatory cascades are activated which cause the formation of toxic intermediates and end products, resulting in further, continuous, and ultimately greater damage than that caused by the initial transient reactive species. Transcription factors such as NF κ B and AP1
5 are activated, which in turn cause production of proinflammatory mediators. These mediators, called cytokines, such as tumor necrosis factor α (TNF α) and various interleukins, cause a burst of free radicals. Arachadonic acid is released, which is itself toxic, and it is oxidized to biologically active mediators. When arachadonic acid is oxidized via the cyclooxygenase or lipoxygenase pathways, for
10 example, prostaglandins, leukotrienes, and hydroxyeicosatetraenoic acid (HETE) are produced, which cause erythema, edema, and additional free radical production accelerating the process. These and other undesirable metabolites permeate and disrupt cell membranes, mitochondrial membranes, and nuclear membranes.

Incessant membrane damage results in cross-linkage or cleavage of
15 proteins and lipoproteins, and oxidation of membrane lipids and lipoproteins. Cell permeability is diminished, intercellular ionic concentration increases, and cellular capacity to excrete or detoxify waste products is decreased. Waste products such as lipofuscin accumulate. The increase in intercellular ionic potassium concentration causes an increase in colloid density, and m-RNA and protein synthesis are
20 hampered, resulting in decreased cellular repair. Some cells become so dehydrated they cannot function at all. Normal metabolic phosphorylation is gradually uncoupled, resulting in cell necrosis and apoptosis. Activation of transcription factors also elicits gene expression of collagenases which cause additional damage. The ultimate result of skin aging is that the regularity of tissue structure is lost.
25 Individual cells enlarge, but the total number of cells decreases by at least approximately 30%. Intercellular collagen increases, and the proportion of soluble collagen decreases. Cross-linking between long-chain collagen macromolecules occurs. Elastin loses its discrete structure and elasticity, and has an increased calcium content. The dermis microscars and diminishes.

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Sunlight and chemical exposure wreaks far greater destruction on the skin than time itself, and intensifies and augments the aging process. There is substantial evidence that ultraviolet radiation induces the formation of reactive oxygen species that trigger the pathways producing toxic intermediates, contributing to the overall metabolic changes described above (Ibbotson, S.H., *et al.*, *J. Investig. Derm.* 112: 933-938, 1999; this paper and others, and the patents cited herein are expressly incorporated in their entireties by reference). Damage to the surface of the skin from sun and chemical exposure is manifested as lines, mottling, discoloration, precancers and cancers.

Early suggestions for dealing with aging and inflammatory effects on skin were predominantly aimed at lubrications and emollients through use of topical compositions containing soothing agents, *e.g.*, commercial hand lotion products. A bewildering variety of skin creams, lotions and ointments are now available over-the-counter, which typically either act to prevent water loss from the skin or to deliver nutrients into the dermal layers. More recently, attention has been directed to agents which address the underlying processes involved in skin damage, such as the underlying free radical generation processes. In this regard, investigations have been made with respect to the antioxidants vitamin E and vitamin C to quench free radicals on the surface of the skin and to protect lipid membranes intracellularly (Wilson, R., *Drug and Cosmetic Industry*, 32-34, 38, and 68, August 1992). Dermatological compositions suggested for the treatment of damaged and aging skin that directly counteract free radical generation metabolic sequelae include tocotrienol preparations (U.S. Pat. No. 5,545,398 to Perricone), precursors of acetylcholine such as dimethylaminoethanol (U.S. Pat. No. 5,554,647 to Perricone), fatty acid esters of ascorbic acid such as ascorbyl palmitate (U.S. Pat. No. 5,574,063 to Perricone), fructose diphosphate (U.S. Pat. No. 6,051,244 to Perricone), catecholamines (U.S. Pat. No. 5,879,690 to Perricone), and polyenylphosphatidylcholine (U.S. Pat. No. 6,191,121 to Perricone).

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Damaged skin may also be removed in chemical peels. Routine medical procedures typically involve the application of particular chemicals such as trichloroacetic acid, resorcinol or salicylic acid, followed by a short reaction time to allow the chemicals to interact with damaged skin areas. Several days later, the damaged areas peel off. Peels can be uneven, however, and sometimes cause other complications such as prolonged inflammation. Less stringent methods have been developed to remedy some of these problems, such as applying trichloroacetic acid with a surfactant and an emulsifier, and then irradiating to obtain a superficial peel (U.S. Pat. No. 4,874,361 to Obagi).

It would be desirable to have mild alternative therapies for skin damage and aging, particularly for sun damage and wrinkles, that can be used instead of, or in addition to, other methods. It would be especially desirable to have skin treatments that continuously counteract the action of proinflammatory and inflammatory cascades involved in inflammation and aging.

BRIEF SUMMARY OF THE INVENTION

It is an objective of this invention to provide methods for treating aging or damaged skin by irradiation of affected skin areas with an effective amount of blue and/or violet visible light having a wavelength of about 400 nm to about 500 nm. The light may be sunlight or artificial light, coherent or noncoherent, pulsed or continuous, of high or low energy, exposed generally or directed to target areas, or any combination of these. A variety of irradiation methods may be employed. In one embodiment, filtered sun or artificial light is used. This can be widely exposed to skin areas, or directed to discrete skin regions, particularly to areas especially susceptible to aging, *e.g.*, the backs of hands and the periorbital and perioral areas of the face. In an alternate embodiment, light-emitting diodes are applied directly to discrete skin areas as needed as patches or thin sheets such as pliable masks. Green light (about 500 to about 590 nm) may be used as adjunct

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therapy with blue/violet light in some embodiments. Compositions containing compounds that enhance light penetration of the stratum corneum such as α -hydroxy acids (*e.g.*, glycolic acid) may be applied to the skin prior to or during phototreatment.

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BRIEF DESCRIPTION OF THE INVENTION

This invention is based on the surprising finding that visible short wavelength blue violet light, which is of a wavelength that typically doesn't penetrate skin well, can provide smoothness and radiance to exposed skin surfaces, resulting in a vibrant, healthy skin appearance, and can resolve erythema such as that produced by the UV effects of sunlight.

Light irradiation on skin and other tissues has been suggested for increasing the growth and proliferation of cells, including the acceleration of wound healing and skin grafts (Grossman, N., *et al.*, *J. Invest. Dermatol.* 102: 649A, 1994), the control of bacterial infection (WO 98/23329 by Lubart), and the treatment of neoplastic diseases (Colussi, V., *et al.*, *Skin Pharm. and Appl. Skin Phys.* 11: 336-346, 1998), pigmentations (including tattoos, U.S. Pat. No. 5,217,455 to Tan), psoriasis (U.S. Pat. No. 5,885,557 to Lentini), and acne (Sigurdsson, V., *et al.*, *Dermatology* 194: 256-260, 1997). These typically involve either UV light (U.S. Pat. No. 3,818,914 to Bender), broad spectrum light having a wavelength between 340 and 3000 nm (*ibid.*), or long wavelength visible orange/red and infrared light (Lubart, R., *et al.*, *J. Photochem. Photobiol B: Biol.* 12: 305-310, 1992 and DE 4,440,112 to Wilkens and Wilkens).

In the practice of the invention, skin is irradiated with blue/violet light having a visible wavelength of about 400 nm to about 500 nm for a time and in amounts and energy levels sufficient to provide an observable effect on the skin comprising a decrease in erythema and/or a decrease in the sensory perception of

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the itching/pain/irritation/warmth described by persons experiencing skin inflammation such as a sunburn, and/or the enhanced appearance of more radiant, vibrant, and healthy skin. The irradiation can be continuous or pulsed, coherent or noncoherent, of high or low intensity, or any combination of these. The light source may be sunlight or generated by artificial means such as lamps, lasers, or light-emitting diodes (LEDs). The blue/violet light may be applied diffusely to exposed skin areas, focused in a pattern corresponding to the configuration of affected areas, targeted to individual especially damaged areas or those particularly susceptible to aging, or delivered to specific skin regions by applying light-emitting diodes in the form of patches or sheets to discrete areas.

A preferred light source for many embodiments is sunlight. Sunlight can be filtered to provide blue violet 400 to 500 nm light using standard optical filters which then provide diffuse blue/green radiation to all of a person's exposed skin surfaces, or, by masking unaffected skin areas, delivered only to selected skin areas that are damaged or inflamed and/or have a tendency to age more than others, such as the eye and mouth regions of the face, the neck, and the backs of the hands. In the practice of this embodiment of the invention, sunlight filters that deliver blue/violet light may be incorporated into beach and picnic table umbrellas, visors, hat brims, and the like conventional devices and garments used by people in the sun. By the same token, blue/violet filters may be incorporated into the structures of sunroom roofs and the roofs of tents used for parties, camping, and eating, and into skylights, particularly the skylights of sunrooms, bathrooms, fitness centers, and indoor swimming pools where the advantages of blue/violet light exposure to skin areas outweighs the possible disadvantages of limiting the visible light spectrum delivered by the skylight to the interior. This aspect of the invention expressly includes skylights with permanent filters that provide exclusively blue/violet light and those that have removable filters that can be controlled to provide blue/violet light at some times, and other light, including full spectrum visible light, at others, such as conventional skylights having blue/violet light

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shutters. Once installed, the filtered light effortlessly provides continuous benefits to the skin.

Other embodiments employ artificial light such as filtered sunlamp and halogen lamps, flash lamps, filtered fluorescent light, including converted red light
5 (e.g., that disclosed in JP 9054562 to Mitsubishi), light arrays (e.g., U.S. 3,818,914, cited above), and light arranged in a pattern corresponding to affected skin areas (e.g., U.S. Pat. No. 5,944,748 to Mager, *et al.*). These can be modified to provide special light distribution devices such as that described by
10 Mori, in U.S. Pat. No. 4,838,271. Also encompassed by the invention are indoor lights equipped with permanent or removable filters; like sunlight filters, artificial light filters may be of particular benefit in bathrooms, fitness centers, indoor swimming pools, *etc.*, and used on fixtures that provide either continuous or occasional blue/violet light, depending upon the light design.

15 As summarized above, LEDs are employed as patches, sheets and the like in alternate embodiments, as these provide an energy source and focused energy delivery to discrete skin areas. Preferred among these are thin, flexible, pliable sheets having embedded LEDS which can be applied to specific regions of the body and are easy to use. One particularly preferred embodiment is an LED
20 face mask, which may have a neck collar as an auxiliary component. An advantage of LED patches or sheets is that they can be easily coupled to optical fibers that simplify light delivery to the treatment region, and the wavelength, pulse length, exposure times, and energy density can be well controlled.

Lasers are used in alternate embodiments, and are a practical light
25 source for some treatments because their high power output at the appropriate wavelength can minimize exposure times. Like LEDs, laser light can be easily coupled to optical fibers that simplify light delivery to the treatment region, and the wavelength, pulse length, exposure times, and energy density can be well

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controlled. Lasers include, but are not limited to, tunable dye or solid-state lasers, metal vapor lasers, and diode lasers.

Light intensity may be varied from high to low, or mixtures thereof. By "low intensity" is generally meant light having an intensity of below about 800 mW per centimeter. By "high intensity" is generally meant light having an intensity of above about 800 mW/cm². A watt is one Joule per second, and optimal irradiation can be gradually and incrementally increased or decreased by 1 to 20 Joules at will or as needed as set out by Tan in U.S. Pat. No. 5,217,455 to achieve optimal results.

Encompassed by the invention are phototreatments that employ green light as adjunct therapy during or after treatment with blue/violet light. By "green" light is meant visible light having a wavelength of about 500 to about 590 nm. Green light may be used together with blue/violet light in some embodiments, either continuously, intermittently, or alternately. In other embodiments, green light therapy is used after the blue/violet light treatment. In embodiments where green light is used, it is delivered by any of the means described above for the delivery of blue/violet light. It is an advantage of this embodiment that green light can be added to phototreatment of the invention simply by slightly enlarging the visible spectrum of the light shone on the skin. It is another advantage of this embodiment that some positive effects reported for green light therapy may be obtained, such as stimulated cellular repair and removal of fine lines and wrinkles, may enhance results obtained using the phototreatment of the invention.

Dermatological compositions containing chemical or physical filters may be administered to skin prior to light therapy in embodiments that employ blue light alone and those that employ blue light and green light. By a "composition containing a chemical filter" is meant compositions containing one or more compounds that screen out light having a wavelength below about 400 nm and above about 500 nm for the embodiment using blue light alone, and one or more

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compounds that screen out light having a wavelength below about 400 nm and above about 590 nm for the embodiment employing blue and green light, in a dermatologically acceptable carrier. By a "composition containing a physical filter" is meant a composition containing fine glass beads, liposomes containing
5 particulate substances that diffract light of certain wavelengths, and the like, in a dermatologically acceptable carrier. In the typical practice of this embodiment of the invention, a cream or lotion composition containing at least one chemical filter and/or at least one physical filter are applied to the skin prior to light therapy according to the invention. It is an advantage of this embodiment that any
10 unfiltered light source may be employed.

One or more active compounds or compositions that enhance light therapy according to the invention, including the chemical and optical transparency of the stratum corneum and, most preferably skin absorption of radiation in the blue violet spectral region between about 400 and about 500 nm, are applied in
15 dermatological compositions prior to or during phototreatments of the invention in some embodiments. As used herein, these agents are collectively called "photopenetration enhancers", and specifically include agents that block visible radiation at wavelengths above the blue/violet region of about 400 to about 500 nm region. Photopenetration enhancers include, but are not limited to, α -hydroxy acids. As
20 used herein, the term " α -hydroxy acid" has reference to and encompasses the general class of organic compounds containing at least one hydroxy group and at least one carboxyl group, and wherein at least one hydroxyl group is located on the α -carbon atom. Typically, the compounds are organic acids having at least one carboxylic acid group and at least one hydroxyl group on the α -carbon atom,
25 and may contain other functional groups including additional hydroxyl and carboxylic acid moieties. Preferred α -hydroxy acids and/or α -hydroxy acid derivatives are less bulky structurally so that they penetrate the skin well, and thus have a backbone of from one to three carbon atoms such as those set out in U.S. Pat. No. 5,965,618 at column 6 lines 4 to 29. Where employed, glycolic and/or

lactic acid or their derivatives are preferred; glycolic acid is especially efficacious.

Where photopenetration enhancers are employed, topical administration to exposed skin sites prior to irradiation is preferred. Only effective amounts are
5 needed to enhance light therapy, and so generally enhancement is achieved by applying the agents to exposed or affected skin sites. This is typically accomplished in association with a carrier, and particularly one in which the agent is soluble *per se* or is effectively solubilized (*e.g.*, as an emulsion or microemulsion). Where employed, the carrier is inert in the sense of not bringing about any
10 adverse effect on the skin areas to which it is applied. Suitable carriers include water, alcohols, oils and the like, chosen for their ability to dissolve or disperse the agents and any other ingredients used in the treatment. Generally, even low concentrations in a carrier are suitable, depending upon the application regimen and adjunct ingredients employed. Many embodiments contain from about 1% to
15 about 15% by weight, more narrowly from about 5% to about 10% by weight photopenetration enhancers. Where glycolic acid is employed as a photopenetration enhancer, typical concentrations range from about 1% to about 10% by weight, more narrowly from about 3% to about 7%, by weight glycolic acid.

20 Compositions containing fat-soluble fatty acid esters of ascorbic acid (vitamin C) may be applied to the skin before, during, or after blue/violet light treatments of the invention. Alternatively, fat-soluble fatty acid esters of ascorbic acid may be added as an adjunct ingredient to compositions containing photopenetration enhancers. The more oxidation-resistant saturated fatty acid esters of
25 ascorbic acid are preferred, including, but not limited to, ascorbyl laurate, ascorbyl myristate, ascorbyl palmitate, ascorbyl stearate, and ascorbyl behenate. Ascorbyl palmitate is used in one embodiment. As denoted herein, where fatty acid esters are described, *e.g.*, ascorbyl stearate, compositions having predominantly that ester, *e.g.*, predominantly stearate, are included. The esters may be
30 prepared using hydrogenated oils or fats, or fractions thereof.

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Preferred methods of the invention are easy to use, non-invasive, and safe. A particular advantage of some embodiments is simplicity. Exposed skin surfaces may be treated for damage and aging by merely sunbathing, gardening, or picnicking outdoors under a blue/violet light filter in an umbrella, hat brim or visor, or in a room with a blue/violet filtered skylight or artificial light. LED masks provide phototherapeutic facials. A further advantage of the invention is that its methods can involve the use of no chemicals applied to hyperallergenic or normal skin.

The efficacy of the light treatment methods of the invention was illustrated in observations involving the exposure of the skin of patients having a sun or chemical burn presenting with a low grade, visibly perceptible erythema. The slightly inflamed skin areas were half masked, and exposed to blue/violet filtered summer sunlight or sunlamp light for two hours. Inflammation in skin regions exposed to blue/violet filtered light resolved in approximately half the time as non-treated skin regions in all individuals. Moreover, most patients reported that phototreated skin areas felt less itchy, irritated, painful, and warm. Individuals with normal skin reported that a two-hour sunbath in blue/violet light made their skin observably smoother, more radiant, vibrant and healthy-looking.

The above description is for the purpose of teaching the person of ordinary skill in the art how to practice the present invention, and it is not intended to detail all those obvious modifications and variations of it which will become apparent to the skilled worker upon reading the description. It is intended, however, that all such obvious modifications and variations be included within the scope of the present invention, which is defined by the following claims. The claims are intended to cover the claimed components and steps in any sequence which is effective to meet the objectives there intended, unless the context specifically indicates the contrary.

CLAIMS

1. A method for treating aging or damaged skin comprising irradiating the skin with an effective amount of visible light having a wavelength of about 400 nm to about 500 nm.
2. A method according to claim 1 wherein the light has an intensity of below about 800 mW/cm².
3. A method according to claim 1 wherein the light has an intensity of above about 800 mW/cm².
4. A method according to claim 1 wherein the light is continuously illuminated on the skin.
5. A method according to claim 1 wherein the light is pulsed.
6. A method according to claim 1 wherein the light is generated from a lamp.
7. A method according to claim 1 wherein the light is filtered sunlight.
8. A method according to claim 1 wherein the light is laser light.
9. A method according to claim 1 wherein the light is emitted from a light-emitting diode.
10. A method according to claim 9 wherein the light-emitting diode is applied directly to the skin as a patch or thin sheet.

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11. A method according to claim 1 wherein the skin is also irradiated with visible light having a wavelength of about 500 to about 590 nm.
12. A method according to claim 1 wherein the skin is treated with a dermatological composition containing a chemical filter prior to irradiation.
13. A method according to claim 1 wherein the skin is treated with a dermatological composition containing a physical filter prior to irradiation.
14. A method according to claim 1 wherein the skin is treated with a dermatological composition that enhances the optical transparency of the stratum corneum prior to irradiation.
15. A method according to claim 14 wherein the composition comprises an α -hydroxy acid.
16. A method according to claim 15 wherein the α -hydroxy acid is glycolic acid.
17. A method for treating aging or damaged skin comprising irradiating the skin with an effective amount of filtered blue/violet sunlight having a wavelength of about 400 nm to about 500 nm.
18. A method according to claim 17 wherein the skin is irradiated through an umbrella, visor, or hat brim comprising a blue/violet filter.
19. A method according to claim 17 wherein the skin is irradiated through a skylight having a blue/green filter.
20. A method for treating aging or damaged skin comprising applying directly to affected skin areas light-emitting diodes that irradiate the skin with visible light having a wavelength of about 400 nm to about 500 nm.

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21. A method according to claim 20 wherein the light-emitting diodes are applied to the skin as skin patches.

22. A method according to claim 20 wherein the light-emitting diodes are applied to the skin in a face mask.

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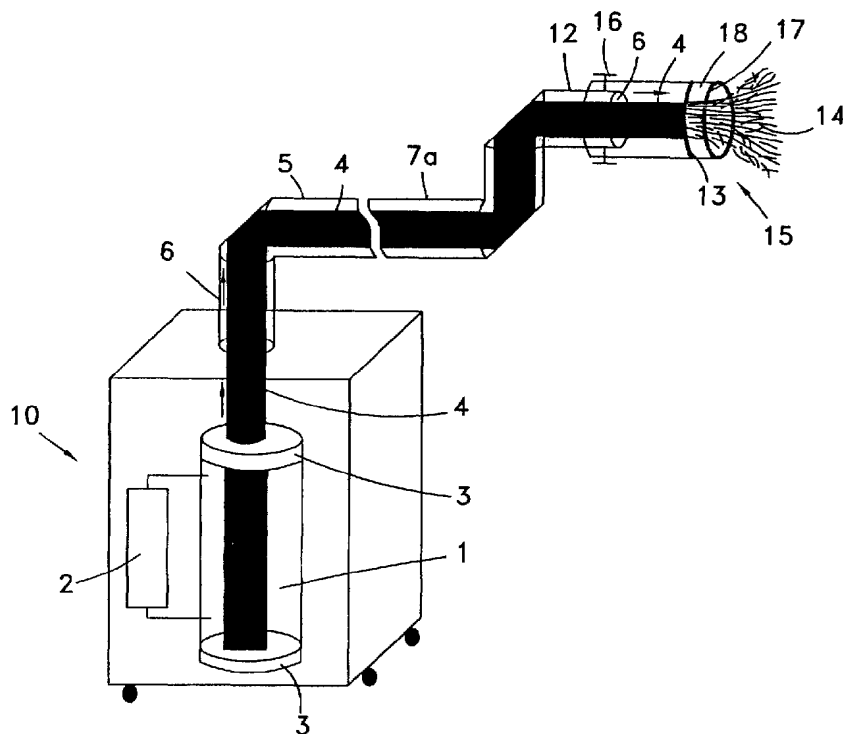
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[IL/IL]; 28 Smadar Street, 46433 Herzlia (IL).
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(54) Title: METHOD AND APPARATUS FOR IMPROVING SAFETY DURING EXPOSURE TO A MONOCHROMATIC LIGHT SOURCE



(57) Abstract: A method and apparatus are disclosed for improving bodily safety during exposure to a monochromatic light source by diverging the monochromatic light, such as with a highly durable diffuser. At a first position of the distal end of the monochromatic light source the energy density of an exit beam from said distal end is substantially equal to the energy density of the monochromatic light required for desired applications and at a second position of the distal end the energy density of the light emitted therefrom is significantly less than the energy density of the monochromatic light. Accordingly, a laser unit suitable for aesthetic treatment, medical treatment or industrial treatment is converted into an eye safe laser unit. Eye safety is further enhanced by measuring the radiance of the divergent monochromatic light and issuing a warning as a result of a mishap if the radiance of the divergent monochromatic light is greater than a predetermined safe value, and if desired, generating a visible flash

prior to the emission of a pulse of monochromatic light to induce an eye of a bystander to blink or to change its field of view in order to avoid staring at the monochromatic light.

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METHOD AND APPARATUS FOR IMPROVING SAFETY DURING EXPOSURE TO A MONOCHROMATIC LIGHT SOURCE

Field of the Invention

The present invention is related to the field of laser-based light sources. More particularly, the present invention is related to providing an eye-safe laser beam that is suitable for correcting aesthetic and medical skin disorders that require a very high energy density. Even more specifically, the present invention is related to a method and apparatus for improving bodily safety during exposure to a monochromatic light source by diverging the monochromatic light, such as with a highly durable diffuser, which provides the required energy density of light for desired applications at a very short distance but is inherently safe to the eyes of bystanders.

Background of the Invention

Current medical and aesthetic laser systems are generally considered as high-risk systems due to the fact that the light beam that is emitted from these systems has only a low divergence, or even convergence. In these systems a light beam with a high energy density and high radiance, i.e. energy density per solid angle, is generated, which hardly attenuates as the beam propagates through air, or through an air-like medium, to a distant target whereat it could cause damage to bodily tissue. In the case of a laser source emitting visible, or near visible, light, damage could result by burning a small portion of an eye retina, if the beam is accidentally aimed at the eyes of a bystander. Such beam could even cause blindness.

Potential eye damage is further increased when using near infrared lasers which emit invisible radiation, since bystanders are unaware that a laser beam is being fired. Also, the extremely short pulse duration of a beam emitted by many laser systems does not allow enough time for one to react, such as by blinking or moving the eyes, as a result of the accidental firing of a laser beam.

Therefore, in order to minimize the risk of damaging living tissues, or causing other kind of damages, special, and often, high-cost precautions must be taken. For example, such precautions might include the use of expensive (and inconvenient to use) coated protective eyeglass filters with very high optical density and damage-resistant values to optical radiation (i.e. thermal and mechanical durability). Some of the properties of such filters are included in standard documents such as ANSI Z136.1, which is the basic American National Standard document regarding the safety of laser beams. A very similar basic document which sets safety labeling standards by the food and drug administration (FDA) is 21 CFR 1040.10 Ch.1. Another document which sets manufacturing standards for the safety of eyes is ISO 15004:1997E. Other precautions forbid using highly reflective surfaces in a room, where the laser system is located. Special shades and/or curtains are also utilized for preventing an accidental laser beam from escaping the room or facility, thereby protecting people outside the treatment room.

Of all the risks, the risk of permanently blinding people is the most common and severe. The currently most eye-hazardous lasers are those referred to as a pulsed-laser. For example, a Ruby, Nd:YAG, Alexandrite, LICA, Diodes, Dye lasers, Erbium-Glass, Excimer lasers, etc. are examples of a pulsed-laser. High-class Continuous Working (CW) lasers, such as Nd:YAG, KTP and Diode lasers (at any wavelength between 630 and 1320 nm) are also known for their risk in causing blindness.

Moreover, these lasers are at times used for cosmetic surgery in the vicinity of the eyes, such as for eyebrow removal or skin rejuvenation around the eyes, and therefore such surgery causes additional risk to eye damage. Other infrared lasers (pulsed and CW), such as diodes operating at 1445 nm wavelength, CO₂ and Erbium, are also capable of causing severe eye damage from a distance by burning the cornea due to the strong absorption of laser beams emitted from such laser sources in the aqueous humor of the eyeball.

There is also a risk of hair and skin burns, if the laser units are mishandled, even if operated in remote locations. Should a collimated laser beam hit a flammable material in the treatment room, a fire may result.

The risks associated with coherent lasers do not stem only from the capability to generate highly collimated beams, but also from the capability to concentrate the entire laser energy onto a confined surface from a distance, with the appropriate focusing optics.

Due to the extremely high thermodynamic temperature of lasers as electromagnetic radiation sources, as compared to the much lower temperature of conventional non-coherent light sources, the efficacy of optical intensity preservation during the focusing or imaging of laser beams, is close to 100%. Conventional non-coherent light sources, although safe to use, cannot be imaged without substantial intensity loss.

All of the above-mentioned risks associated with visible and near infrared lasers have led to very strict governmental regulations regarding the operation of medical and aesthetic laser-based systems, causing a substantial increase in the expenses of both manufacturers and operators of these systems. According to some of these governmental regulations, the

operation of laser devices/systems is restricted to trained and skilled personnel, i.e. technicians or nurses under the supervision of a physician. In many countries, non-medical personnel such as cosmeticians are not allowed to handle laser-based systems at all. As a result the laser cosmetic business volume is restricted to a small fraction of its potential volume.

According to some aspects of medical and cosmetic laser systems, the treatment is focused on selected targets at the outer surface of the skin or within the skin. Each of these targets, for example, hair, vascular lesions, pigmented lesions, tattoos, acne, mild collagen damages resulting in fine wrinkles, and sun-damaged skins, have different optical spectral absorption characteristics. Therefore, these applications utilize laser systems that are capable of generating visible or near infrared light having a wavelength within the range of 310-1600 nm. There exists, therefore, a risk of directing a laser beam having an incorrect wavelength to a selected treated organ/tissue, which may severely damage this organ/tissue. Even if the organ is treated by a laser beam having the correct wavelength, there is always a risk that the laser beam might be mistakenly aimed to other areas, which are highly sensitive to the selected wavelength, thereby resulting in damage.

As opposed to laser systems, non-laser incoherent diffused sources, such as Intense Pulsed Light (IPL) sources, which are based on high voltage arc lamps, are generally considered to be damage-safe from a distance, since IPL systems have a limited light source temperature, usually in the range of 1000- 10,000 °C, and are consequently of limited brightness and are not focusable to small spots, in contrast to as high as 1,000,000 °C in laser systems. However, IPL systems have reduced spectral selectivity due to their broad spectral bands. Consequently, IPL-based systems offer rather limited treatment capabilities in comparison to laser-based systems.

US 6,197,020 and US 6,096,029 disclose imaging of a focusing, diffusing light plate, such as from the distal surface of a bundle of optical fibers at a distance beyond the system, in order to focus the beam below the tissue surface. The systems disclosed herein are also extremely risky to the eyes since the laser energy density is essentially preserved within a relatively small solid angle to which an eye may be exposed, even after having transporting the beam to a distal confined spot. As opposed to the present invention, these two patents conform to state of the art treatments by which the focusing of a laser beam to subcutaneous locations beyond the distal end of the treatment system is acceptable. The generation of a laser beam having a large divergent solid angle is disadvantageous, according to prior art methods, particularly since efficient imaging and focusing on the skin or into the skin would be precluded. Also, the laser energy density associated with these two patents is efficacious only when the diffusing, focusing plate is at a distance from a target, and is not efficacious when located adjacent to a target.

G. Vargas and A. J. Welch, in their article "Effects of Tissue Optical Clearing Agents on the Focusing Ability of Laser Light within Tissue" ("Lasers in Surgery and Medicine", Supplement 13, 2001, p. 26) describe techniques for reducing the scattering of light energy within a tissue, in order to provide for a more focused spot and, thus, more efficient treatment of dermal lesions. However, as already described, there is a trade-off between the efficiency of a laser device and the potential risk in its operation; i.e., as the beam is more focused, the treatment becomes more risky.

Other relevant prior art is disclosed in US Patent Nos. 5,595,568, 5,879,346, 5,226,907, 5,066,293, 5,312,395, 5,217,455, 4,976,709, 6,120,497, 5,411,502, 5,558,660, 5,655,547, 5,626,631, 5,344,418,

5,964,749, 4,736,743, 5,449,354, 5,527,308, 5,814,041, 5,595,568, 5,735,844, 5,057,104, 5,282,797, 6,011,890, 5,745,519, and 6,142,650.

The prior art laser units are not capable of generating a beam with a high energy level that may be used for aesthetic or surgical procedures without presenting a risk of injury to bystanders or damage to property, such as by igniting a fire.

It is an object of the present invention to provide a laser beam that may be used for aesthetic or surgical procedures.

It is an object of the present invention to provide a laser beam that overcomes the disadvantages of the prior art.

It is another object of the present invention to provide a laser beam that is not injurious to an operator, observer or to objects located in the vicinity of or at a distance from a target.

It is an additional object of the present invention to provide a laser beam that may be used for industrial applications.

It is yet another object of the present invention to provide a unit of optical elements that provides wide angle diffusion with high thermal durability

Other objects and advantages of the invention will become apparent as the description proceeds.

Summary of the Invention

The present invention comprises a method of improving bodily safety of bystanders exposed to a monochromatic light source, comprising: providing a monochromatic light source with a distal end, causing said

monochromatic light to diverge at said distal end, whereby at a first position of said distal end relative to a target the energy density of an exit beam from said distal end is substantially equal to the energy density of the monochromatic light and at a second position of the distal end relative to a target the energy density of the light emitted from said distal end is significantly less than the energy density of the monochromatic light.

As referred to herein, monochromatic light is defined as being divergent when its exit angle from the distal end of the monochromatic light source, or from the distal end of a diverging unit, when used, is greater than a half angle of 6 degrees, wherein a "half angle" is defined as the half angle measured on a plane perpendicular to the propagation axis of a collimated beam generated by the monochromatic light source. With such a divergent angle, protective eyeglasses having an optical density approximately of only 2 are required for the aesthetic laser types specified hereinafter, corresponding to a transmittance of 1%. When the divergent half angle is 20 degrees, protective eyeglasses with an optical density of 1 are required, corresponding to a transmittance of 10%. When the divergent half angle is 60 degrees, no protective eyeglasses are required.

As referred to herein, "distal" is defined as a direction towards the exit of a monochromatic light source, or of a unit attached to the latter, when used, and "proximate" is defined as a direction opposite from a distal direction.

The method preferably further comprises the steps of:

- a) providing a diverging unit transparent to the monochromatic light unit comprising at least one focusing lens, a plurality of reflectors and a distally positioned plate transparent to the monochromatic light;
- b) attaching said diverging unit to the distal end of the monochromatic light source;

- c) focusing the monochromatic light onto at least one of said reflectors; and
- d) allowing light rays to exit said plate at varying angles, depending on the number of times reflected by said reflectors, whereby to cause said monochromatic light to be divergent.

In one preferred embodiment, the method further comprises the step of scattering the monochromatic light, said scattered monochromatic light being divergent.

As referred to herein, "scattered" monochromatic light is defined as light whose direction has randomly changed by reflection or refraction from discontinuities in the medium through which it propagates, without any substantial change in the wavelength of the incident light.

In one aspect, scattering is accomplished by

- a) providing a diffusing unit with a distal end, said diffusing unit comprising at least one diffusively transmitting element, wherein each of said diffusively transmitting elements is transparent to the monochromatic light;
- b) attaching said diffusing unit to the distal end of the monochromatic light source; and
- c) allowing the monochromatic light to be scattered by each of said diffusively transmitting elements.

In another aspect, scattering is accomplished by

- a) providing a diffusing unit transparent to the monochromatic light comprising an angular beam expander and at least one diffuser;
- b) attaching said diffusing unit to the distal end of the monochromatic light source; and

c) allowing the monochromatic light to propagate through said angular beam expander and said at least one diffuser, whereby to scatter said monochromatic light.

In one aspect, scattering is accomplished by

- a) providing a diffusing unit with a plurality of diffusers, wherein at least one diffuser is axially displaceable;
- b) axially displacing said at least one axially displaceable diffuser to an active position such that each diffuser is substantially in contact one with the other, whereby the energy density of an exit beam from said diffusing unit is substantially equal to the energy density of the monochromatic light at the first position of the distal end of the monochromatic light source; and
- c) axially displacing said at least one axially displaceable diffuser to an inactive position such that each diffuser is separated one from the other by a gap large enough to generate a sufficiently large scattering angle such that the energy density of the light emitted from said diffusing unit at the second position of the distal end of the monochromatic light source is significantly less than the energy density of the monochromatic light.

Preferably, the first position of the distal end of the monochromatic light source is substantially in contact with a target to which the monochromatic light is directed.

In one aspect, the radiance of the divergent monochromatic light is less than $14 \text{ J/cm}^2/\text{sr}$. In another aspect, the radiance of the divergent monochromatic light is less than $10 \cdot k_1 \cdot k_2 \cdot (t^{1/3}) \text{ J/cm}^2/\text{sr}$, where t is a laser pulse duration in seconds, $k_1 = k_2 = 1$ for a wavelength ranging from 400 to 700 nm, $k_1 = 1.25$ and $k_2 = 1$ for a wavelength of approximately 750 nm, $k_1 = 1.6$ and $k_2 = 1$ for a wavelength of approximately 810 nm, $k_1 = 3$ and

$k_2=1$ for a wavelength of approximately 940 nm, and $k_1=5$ and $k_2=1$ for a wavelength ranging from 1060 to 1400 nm.

As referred to herein, "radiance" is defined as the energy density divided by solid angle, wherein energy density is radiant energy per projected area. The value of a solid angle is given in units of steradians, normally symbolized as "sr."

The method further comprises measuring the radiance of the divergent monochromatic light and issuing a warning as a result of a mishap if the radiance of the divergent monochromatic light is greater than a predetermined safe value.

The monochromatic light is selected from the group of collimated laser beam, convergent laser beam, concentrated multiple laser beams and fiber guided laser beam.

The monochromatic light source is selected from the group of Excimer, Dye, Nd:YAG 1064, 1320 and 1440 nm, frequency doubled Nd:YAG, Ruby, Alexandrite, Diode including diodes operating at a wavelength of 810 to 830 nm, 940nm, and 1450nm, stack of diodes, LICAF, Er:Glass, Er:YAG, Er:YSGG, CO₂, isotopic CO₂ and Holmium lasers.

The monochromatic light is provided with a wavelength ranging from 308 to 1600 nm or between 1750 nm to 11.5 microns and the energy density level of the monochromatic light source ranges from 0.01 to 2000 J/cm².

In one aspect, the monochromatic light source is a plurality of monochromatic diodes.

The bodily safety includes eye safety, skin safety and environmental safety.

The exit beam at the first position is used in applications selected from the group of cosmetic applications, medical applications and industrial applications.

The exit beam at the first position is used in applications selected from the group of hair removal, coagulation of blood vessels located on a face or legs, treatment of rosacea, tattoo removal, removal of pigmented lesions in the skin, skin rejuvenation, treatment of psoriasis, treatment of acne, skin resurfacing, skin vaporization, collagen contraction, dental applications, removal of pigments from the gums, teeth whitening, dermatology, gynecology, podiatry, urology, reduction of pain, laser welding of transparent plastic materials, surface treating of materials, laser annealing, evaporation of paint and ink stains and cleaning of buildings, stones, antique sculptures and pottery.

In one aspect, a laser beam is controllably repositionable to scan targets of the diffusively transmitting element, wherein the sequence of targets to be impinged by the laser beam is programmable.

The duration of a laser pulse ranges from 1 nanosecond to 1500 msec, and the diameter of a spot size ranges from 1 to 20 mm. If so desired, a series of pulses is generated.

The present invention also comprises a method for converting a laser unit suitable for aesthetic treatment, medical treatment or industrial treatment into an eye safe laser unit, comprising attaching a diverging optical unit to the distal end of a laser unit, allowing monochromatic light to propagate through said unit, generating a non-coherent and extended

diffused source of light from said unit at a sufficiently low radiance value such that said source of light is eye safe to bystanders exposed to a monochromatic light source and of a sufficiently high energy density at a treatment location to effect said aesthetic treatment, medical treatment or industrial treatment.

In one aspect, the unit is a divergent diffusing optical unit.

The present invention also comprises a method of cooling skin which is irradiated with monochromatic light, comprising:

- a) providing a monochromatic light source with a distal end;
- b) providing a unit with two transmitting elements that are transparent to monochromatic light, such that a gap is formed between said two elements;
- c) attaching said unit to the distal end of the monochromatic light source;
- d) placing said unit on a skin location to be treated;
- e) providing means for skin cooling, said skin cooling means being disposed within said gap;
- f) allowing monochromatic light to propagate through said unit to said skin location, the temperature of the skin location to be treated thereby increasing; and
- g) allowing said skin cooling means to cool said skin location.

The method preferably further comprises the following steps:

- a) providing the unit with a diffusively transmitting element and with a clear transmitting element distally positioned with respect to said diffusively transmitting element;
- b) allowing the monochromatic light to be scattered by said diffusively transmitting element, whereby the energy density of an exit

beam from said clear transmitting element is substantially equal to the energy density of the monochromatic light; and

c) repositioning the unit from the target to a predetermined position at which the energy density of an exit beam from said diffusively transmitting element is significantly less than the energy density of the monochromatic light.

In one aspect, the skin cooling means is fluid transparent to the monochromatic light, said fluid flowing through a conduit inserted within the gap. The fluid may be in fluid communication with an external cooler.

In another aspect, the skin cooling means is a thermoelectric cooler, the thermoelectric cooler operative to cool the lateral sides of the transmission element placed on the skin location to be treated.

The present invention also comprises a method of improving eye safety during exposure to a monochromatic light source, comprising: providing a monochromatic light source and generating a visible flash prior to the emission of a pulse of monochromatic light, thereby inducing an eye of a bystander to blink or to change its field of view in order to avoid staring at the monochromatic light.

Preferably, the generation of the visible flash is synchronized to the timing of the emission of the monochromatic light pulse, wherein the duration of the pulse is shorter than an eye blinking response time.

The monochromatic light source is suitable for hair removal, photorejuvenation or treatment of vascular lesions.

The present invention comprises an apparatus for improving bodily safety of bystanders exposed to a monochromatic light source, comprising a

means attached to the distal end of a monochromatic light source, said means adapted to cause the monochromatic light to be divergent, whereby at a first position of said distal end relative to a target the energy density of an exit beam from said distal end is substantially equal to the energy density of the monochromatic light and at a second position of said distal end relative to a target the energy density of the light emitted from said distal end is significantly less than the energy density of the monochromatic light.

In one aspect, the diverging means comprises a diverging unit provided with at least one focusing lens, a plurality of reflectors and a distally positioned plate transparent to the monochromatic light, each of said at least one lens provided with a suitable focal length so as to focus the monochromatic light onto at least one of said reflectors, each of said reflectors positioned so as to allow light rays to exit said plate at varying angles, depending on the number of times reflected by said plurality of reflectors, whereby to cause said monochromatic light to be divergent.

In one embodiment, the diverging means is also a scattering means.

In one aspect, the scattering means comprises a diffusing unit attachable to the distal end of the monochromatic light source, said diffusing unit including at least one diffusively transmitting element that is transparent to essentially coherent monochromatic light.

The material of each diffusively transmitting element is selected from the group of silica, glass, sapphire, diamond, non-absorbing polymer, light diffusing polymer, polycarbonate, acrylic, densely packed fibers, NaCl, CaF_2 , glass, ZnSe and BaF_2 .

In one aspect, the diffusing unit is further provided with a clear transmitting element distal to a diffusively transmitting element, the diffusively transmitting element and clear transmitting elements being mutually parallel and perpendicular to the longitudinal axis of the diffusing unit.

The clear transmitting element is made of a material selected from the group of glass, sapphire, transparent polymer including polycarbonate and acrylic, BaF_2 , NaCl and ZnF_2 .

A gap between the diffusively transmitting and clear transmitting elements is preferably less than 2 mm.

Each diffusively transmitting element may be provided with a plurality of irregularities which are randomly distributed thereabout.

The diffusively transmitting element may also be formed by a diffraction pattern or by a randomly distributed array of thin fibers.

In another aspect, the scattering means comprises a diffusing unit attachable to the distal end of the monochromatic light source, said diffusing unit including an angular beam expander and at least one diffuser.

An angular beam expander preferably comprises at least one light guide, each of said light guides being provided with internally reflecting walls and an exit surface. A light guide is made of a material selected from the group of solid glass, sapphire, plastic and liquid dielectric material, and may be tapered.

An angular beam expander may also comprise an optical element which increases the divergence angle of monochromatic light and a diffuser which receives light from said optical element and emits said received light to the light guide, the exit surface of said light guide functioning as a wide angle extended diffuser source.

In another aspect, the scattering means comprises a diffusing unit attachable to the distal end of the monochromatic light source, said diffusing unit comprising a plurality of diffusers wherein at least one is axially displaceable, such that at an active position the plurality of diffusers are substantially in contact one with the other at the first position of the distal end of the monochromatic light source, and the energy density of an exit beam from said diffusing unit is substantially equal to the energy density of the monochromatic light, and at an inactive position each of said diffusers is separated one from the other by a gap such that the energy density of the light emitted from the diffusing unit is significantly less than the energy density of the monochromatic light at the second position of the distal end of the diffusing unit.

The duration of a laser pulse ranges from 1 nanosecond to 1500 msec.

A laser unit is provided with a power level ranging from 1 to 2000 W, when under continuously working operation.

In one aspect, the apparatus further comprises a plurality of reflectors, the angular disposition and distance of each reflector relative to the diffusing unit being repositionable, whereby to accurately direct the monochromatic light to a selected target on the diffusively transmitting element. A processor is preferably provided, said processor suitable for the programming of the sequence of targets to be impinged by the monochromatic light. A scanner is also preferably provided for rapid

repositioning of the monochromatic light to a target on the diffusively transmitting element.

In one aspect, the distance between a distal end of the diverging means and the target at the first position of the distal end of the monochromatic light source is the smaller of 2 mm and the diameter of the monochromatic light.

A diffusing or diverging unit is attached to the distal end of the monochromatic light source by an attachment means.

In one aspect, the unit is fixedly attached to the distal end of the monochromatic light source.

In one aspect, the unit is integrally formed together with the distal end of the monochromatic light source during manufacturing, the unit being disposed internally to the outer wall of the monochromatic light source.

In another aspect, the attachment means is releasable. For example, the attachment means is permanently attached to the monochromatic light source and displaceable, whereby in one position of a displaceable unit the monochromatic light source is coherent, not propagating through said displaceable unit, and in a second position at which said displaceable unit is attached to the distal end of the monochromatic light source, the monochromatic light is noncoherent, propagating through the displaceable unit.

Preferably, the apparatus further comprises a means to evacuate vapors or particles from a target to thereby prevent a change in optical properties of the unit. The evacuation means is U-shaped in vertical cross-transmission element, to allow for contact with a target at its lateral ends and for

evacuation of vapors or particles through a gap formed by its central open region.

In one aspect, the evacuation means further comprising a relay optics device, whereby to concentrate the exit beam from the unit onto the target.

The present invention also comprises an apparatus for cooling skin which is irradiated with monochromatic light, comprising:

- a) a monochromatic light source with a distal end;
- b) a unit attachable to the distal end of the monochromatic light source, said unit being provided with two elements that are transparent to monochromatic light, such that a gap is formed between said two elements; and
- c) a means for skin cooling insertable within said gap, said skin cooling means adapted to reduce the rate of increase of temperature at a target skin location.

In one aspect, one element is a diffusively transmitting element and the other element is a clear transmitting element distally positioned with respect to said diffusively transmitting element, whereby the energy density of an exit beam from the diffusing unit is substantially equal to the energy density of the monochromatic light upon placement of the diffusing unit at a position adjacent to a target skin location and is significantly less than the energy density of the monochromatic light at a distance from said target.

In one aspect, the skin cooling means is a fluid transparent to said monochromatic light, said fluid flowable through a conduit inserted within the gap. Preferably, the fluid is in fluid communication with an external cooler.

In one aspect, the fluid is a liquid or a gas.

In another aspect, the skin cooling means is a thermoelectric cooler, the thermoelectric cooler operative to cool the lateral sides of the element placed adjacent to the skin location to be treated.

In another aspect, the apparatus comprises a scanner, said scanner being adapted to rapidly reposition the monochromatic light to a target on the diffusively transmitting element, the skin cooling means capable of continuously cooling the skin at a corresponding target skin location.

The present invention also comprises an apparatus for improving eye safety during exposure to a monochromatic light source, comprising: a monochromatic light source, a means for generating a visible flash prior to emission of a monochromatic light, and control circuitry in communication with said means for generating a visible flash.

The control circuitry is preferably synchronized such that the flash is generated prior to the emission of each pulse of monochromatic light, thereby inducing an eye of a bystander to blink or to change its field of view in order to avoid staring at the monochromatic light.

The duration of the pulse is preferably shorter than an eye blinking response time.

Brief Description of the Drawings

In the drawings:

- Fig. 1 illustrates a side view of various laser units equipped with a diffusing unit, in accordance with the present invention, wherein the delivery system shown in Fig. 1a is an articulated arm, in Fig. 1b is an optical fiber and in Fig. 1c is a conical light guide;

- Fig. 2 illustrates a side view of the distal end of a laser unit, showing how the diffusing unit is attached thereto, wherein the diffusing unit is externally attached to the guide tube in Fig. 2a, is attached to a pointer in Fig. 2b, is releasably attached to the guide tube in Fig. 2c, is integrally formed together with the guide tube in Fig. 2d and is displaceable in Fig. 2e whereby at one position the exit beam propagates therethrough and at a second position the exit beam does not propagate therethrough;

- Fig. 3 is a schematic diagram of various configurations of prior art laser units, wherein Fig. 3a shows a non-scattered beam directed by reflectors to a target, Fig. 3b shows a non-scattered beam directed by an optical fiber to a target, Fig. 3c illustrates prior art surgery performed with a laser beam and scanner, Fig. 3d shows the propagation of prior art refracted laser beams towards a blood vessel, Fig. 3e shows an ablative laser beam focused on tissue in conjunction with a scanner, and Fig. 3f shows the formation of a crater in tissue by an ablative beam;

- Fig. 4 is a schematic diagram illustrating the advantages of employing a diffusing unit of the present invention, wherein Fig. 4a shows the relative location of the diffusing unit, Fig. 4b shows that a collimated laser beam is transformed into a randomly scattered beam, Fig. 4c shows that a scattered beam reduces risk of injury to the skin and Fig. 4d shows that a collimated laser beam reduces risk of injury to the eyes;

- Fig. 5 is a schematic drawing showing the propagation of a laser beam towards a blood vessel, wherein Fig. 5a shows the propagation of an unscattered laser beam towards a blood vessel, Fig. 5b shows the propagation of a scattered laser beam towards a blood vessel, Fig. 5c illustrates the formation of an ablation by means of an unscattered laser beam. Fig. 5d illustrates the formation of an ablation by means of an scattered laser beam in accordance with the present invention, and Fig. 5e illustrates the scattering of a laser beam distant from a blood vessel;

- Fig. 6a is a schematic drawing showing the accumulation of liquid residue on a diffusively transmitting element and Fig. 6b is a schematic drawing in which a diffusively transmitting element is shown to be mounted within a hermetically sealed diffusing unit;
- Fig. 7 illustrates the production of a plurality of microlenses, wherein Fig. 7a illustrates the sandblasting of a metallic plate, Fig. 7b illustrates the addition of a liquid sensitive to ultraviolet light, Fig. 7c illustrates the removal of the metallic plate and Fig. 7d illustrates the generation of a scattered laser beam through the microlenses;
- Fig. 8 illustrates two types of a diffusing unit, wherein Fig. 8a illustrates one employing a single wide angle diffuser and Fig. 8b illustrates one employing a small angle diffuser;
- Fig. 9 illustrates a diffusing unit which employs a tapered light guide, such that the light guide receives monochromatic light from an optical fiber in Fig. 9a and from an array of microlenses in Fig. 9b;
- Fig. 10 illustrates a diffusing unit which utilizes an angular beam expander without a light guide in Fig. 10a and with a light guide in Fig. 10b;
- Fig. 11 illustrates a diffusing unit which employs two holographic diffusers, each of which is attached to a corresponding light guide;
- Fig. 12 illustrates a diffusing unit which includes two diffusers, one of which is axially displaceable, wherein Fig. 12a illustrates the unit in an active position and Fig. 12b in an inactive position;
- Fig. 13 is a schematic drawing of another preferred embodiment of the present invention in which a scanner rapidly repositions a coherent laser beam onto a plurality of targets on a diffusively transmitting element;
- Fig. 14 is another preferred embodiment of the present invention in which a non-scattering diverging unit is used to diverge an input laser beam, wherein Fig. 14a illustrates a single optical element and Fig. 14b illustrates a plurality of elements;

- Fig. 15 is a schematic diagram of various means of cooling skin during laser-assisted cosmetic surgery, wherein Figs. 15a-d are prior art means, while Fig. 15e utilizes cooling fluid and Fig. 15f utilizes a thermoelectric cooler;
- Fig. 16 illustrates an eye safety measurement device; and
- Fig. 17 is a schematic drawing of a flashing device, wherein Fig. 17a illustrates one that induces uncontrolled blinking before firing a laser beam, Fig. 17b is a timing diagram corresponding to the flashing device of Fig. 17a, and 17c illustrates a flashing device that detects a retroreflected beam from an eye within firing range of a laser beam.

Detailed Description of Preferred Embodiments

Fig. 1a illustrates a high-intensity laser unit, generally designated by 10, which is suitable for use with the present invention. Laser unit 10 operates at a wavelength ranging between 300 and 1600 nm or between 1750nm and 11.5 microns, either pulsed, with a pulse duration of 1 nanosecond to 1500 milliseconds and an energy density of 0.01-200 J/cm², or continuous working with a power density higher than 1 W/cm². Laser unit 10 is provided with a diffusing unit, generally designated by 15, which induces the exit beam to be scattered. An exit beam is considered to be scattered according to this embodiment when its average half angle angular divergence is greater than 42 degrees relative to the propagation axis of collimated beam 4. A half angle of 60 degrees corresponds to the half angle generated by an "ideal transmitting diffuser," which herein refers to a diffuser with 100% transmission and is provided with Lambertian angular scattering properties. Such a scattering angle, in accordance with the present invention, allows the light which exits diffusing unit 15 to be safe to the eyes of a bystander, yet is provided with a sufficiently high energy density which is necessary for the clinical efficacy of the laser unit.

Laser unit 10 comprises amplifying medium 1 activated by power supply 2 for increasing the intensity of a light beam and two parallel mirrors 3 that provide feedback of the amplified beam into the amplifying medium, thereby generating a coherent beam of ultrapure frequency. The laser unit emits a coherent beam 4 which propagates through a delivery system 5 to distal end 6. The delivery system depicted in Fig. 1a is articulated arm 7a. Diffusing unit 15 is fixedly attached to the distal end of guidance tube 12 by attachment means 16, which may be a set of screws or by bonding or other means known to those skilled in the art, thereby inducing non-coherent randomly scattered beam 14 associated with a narrow spectral bandwidth that does not present any risk of damage to bodily tissue if the laser is inadvertently directed to an incorrect target. The diffusing unit includes a passive refractive element that preserves the wavelength of coherent beam 4, as well as its narrow bandwidth, which is generally less than one Angstrom.

In one preferred embodiment of the invention, diffusing unit 15 is preferably cylindrical or rectangular, although any other geometrical shape is equally suitable, and comprises diffusively transmitting element 13, which is proximate to distal end 6 of the laser unit and clear transmitting element 17. Both diffusively transmitting element 13 and clear transmitting element 17 have the same dimensions and are bonded to diffusing unit 15. Diffusively transmitting element 13 and clear transmitting element 17 are preferably separated by narrow gap 18. Due to the existence of gap 18, the laser beam will remain scattered even if clear transmitting element 17 shatters, thereby preserving the inherent safety of a laser unit that incorporates the present invention. The width of gap 18 is as small as possible, usually 0.1 mm. However, diffusing unit 15 may be adapted to a configuration in which diffusively transmitting element 13 contacts clear transmitting element 17. Alternatively, diffusing unit may be provided without a clear transmitting element, whereby the

frosted surface of diffusively transmitting element 13 faces the laser unit and its smooth surface faces the tissue.

Scattering is achieved by means of minute irregularities of a non-uniform diameter formed on the substrate of diffusively transmitting element 13. Diffusively transmitting element 13 is preferably produced from thin sand blasted or chemically etched glass, e.g. having a thickness from 0.1 to 0.2 mm, or a thin sheet of non-absorbing light diffusing polymer, e.g. having a thickness of less than 50 microns, such as light diffusing polycarbonate, Mylar or acrylic.

A diffusively transmitting element may also be produced by using a large angle holographic diffuser such as one produced by Physical Optics Corporation (PCO), USA, and is placed adjacent to an additional diffuser. A holographic diffuser illustrated in Fig. 11 induces a scattering half angle, for example, of at least 40 degrees and the second diffuser additionally induces the scattering so as to attain a scattering half angle of e.g. 60 degrees.

A diffuser which approaches an ideal transmitting diffuser and induces a scattering half angle of 60 degrees and a scattering solid angle of 3.14 sr may be produced from material such as acrylic or polycarbonate by pressing the material against an appropriate surface provided with a very dense array of Frensel microlenses, such as those produced by Fresnel Technologies Inc., USA, or by placing arrays of microlenses surfaces separated from a light guide as depicted in figures 9b.

Similarly diffusively transmitting element 13 may be produced from light diffusing paper such as transparent "Pergament" drawing paper, and may also be produced from other materials such as ZnSe, BaF₂, and NaCl, depending on the application and the type of laser used. Both faces of clear

transmitting element 17 are essentially planar and smooth. Clear transmitting element 17, which is capable of withstanding the thermal stress imposed by a scattered laser beam, is transparent and made from sapphire, glass, a polymer such as polycarbonate or acrylic, and may be produced from other materials as well, such as ZnF_2 .

Diffusively transmitting element 13 may be chilled so that it will be capable of withstanding the high power densities which are necessary for attaining clinical efficacy.

As depicted in Fig. 1b, the delivery system may also be optical fiber 7b into which laser beam 4 is focused. Diffusing unit 15 is mounted on guidance tube 8, which directs the beam exiting the distal end of optical fiber 7b by attachment means 16. Furthermore, as depicted in Fig. 1c, the laser unit may be comprised of array 11 of miniature lasers, such as those provided with high power diode lasers, e.g. the Lightsheer produced by Coherent, USA, for hair removal. The beam delivery system for this configuration is preferably conical reflector 7c. In this configuration, diffusing unit 15 is fixed to distal end 6 of light guide 7c and transforms a high-risk beam into randomly scattered beam 14.

Figure 2 illustrates various methods by which diffusing unit 15 is attached to a laser unit. In Fig. 2a, bracket 19 which supports diffusing unit 15 is attached to guidance tube 12 of an existing laser unit, such as one in use in a clinic, by attachment means 16a, which may be a set of screws or by bonding. As shown in Fig. 2b the laser unit is provided with pointer 31, or any other equivalent subdiffusing unit which enables the user to direct beam 4 to a desired target on the skin, by the focal length and beam diameter which are dictated by lens 9 mounted within guidance tube 12. In this alternative, diffusing unit 15 may be externally attached to guidance tube 12, or may be attached to pointer 19. In Fig. 2c, diffusing

unit 15 is attached to Velcro tape 16c, or another type of adhesive tape. This type of attachment means is sufficient for temporary usage. In Fig. 2d, diffusing unit 15 is integrally formed together with guidance tube 12 during manufacturing, internal to the outer wall thereof. Fig. 2e illustrates a releasable attachment means, whereby in one position of a displaceable diffusing unit the exit beam is coherent, not propagating through a diffusively transmitting element, and in a second position in which diffusing unit 15 is attached to guidance tube 12, the exit beam is noncoherent and propagates through a diffusively transmitting element.

In prior art cosmetic laser surgery, as shown in Fig. 3a, laser unit 20 emits a non-scattered coherent beam 24 from distal end 23 via reflectors 21, 22, by optical fiber 29 in Fig. 3b, or alternatively by deflectors 27 as shown in Fig. 3c, to site 26 that is to be treated within tissue 25. Following the surgery, a well-defined spot is generally produced having a size of up to 20 mm, depending on the specific application and device. Furthermore, beam 24 may be directed by means of motor 28 as shown in Fig. 3c in those situations in which extensive surgery is desired and tissue 25 needs to be scanned. When the wavelength ranges from 310-1600 nm, i.e. ultraviolet and near-infrared, the beam is scattered into individual rays 30, as shown in Fig. 3d, while propagating to blood vessel 32 from site 26. Blood vessel 32 is presented as an example and could be replaced by a hair follicle or any type of skin lesion. At wavelengths ranging from 1750 nm to 11.5 microns, i.e. far infrared, lasers are often used in focused pin-point ablation, that is, having a diameter ranging from 50-200 microns at a shallow depth of 20-150 microns, of epidermal or papillary dermal tissue in conjunction with a scanner, as shown in Fig. 3e. The lasers are used mainly for ablation of tissue, the formation of a crater shown in Fig. 3f. Laser 20, which is capable of effecting the desired surgery at a large distance between distal end 23 and target site 26 for the various applications shown in Figs. 3a-d, nevertheless can cause severe damage if the beam is not properly aimed.

In contrast, the present invention, which is schematically depicted in Fig. 4, presents a much lower risk to the patient and to observers. As shown in Fig. 4a, diffusing unit 15 is attached to distal end 23 of the laser unit. Diffusing unit 15 transforms the coherent, usually collimated laser beam 24 into homogeneous, randomly scattered beam 14 shown in Fig. 4b. As a result beam 14 significantly reduces risk of injury to the skin as shown in Fig. 4c or to the eyes as shown in Fig. 4d since a collimated beam is not directed to these parts of the body. At very short distances of less than one tenth of the diameter of beam 24 from distal end 23, beam 24 has not begun to completely scatter and increase its diameter and is therefore efficacious as a means for performing cosmetic surgery as shown in Fig. 4c, although an increase in the laser power level may sometimes be needed to compensate for reverse reflections from the diffusing unit into the laser unit. Compensation, in terms of an increase in the needed power level for the laser unit, for reverse reflections is usually be close to 16% due to four air-glass interfaces with 4% Fresnel reflection, and at times may attain 50%. An anti-reflection coating may be used to reduce reflection. For laser units which operate at approximately 10-20% of their maximum energy capacity, it is possible to place the exit plane of the diffusing unit, whether a frosted or clear transmitting element, at a distance from the skin corresponding to approximately 50% of the exit beam diameter.

Fig. 5 demonstrates the advantages of the present invention. Fig. 5a illustrates conventional coherent laser beam 24 at a wavelength of 308 to 1600 nm. The collimated beam contacts tissue 25 at a diameter of D before being scattered into individual rays 30 during propagation to target destination 32. Fig. 5b illustrates the result of attaching diffusing unit 15 to the laser unit. When diffusing unit 15 is disposed at a small distance from the tissue surface, the diameter of the scattered beam which contacts tissue 25 is increased by a negligible value of Δd , assuming uniform

scattering, in comparison with the original beam diameter of D . If the thickness t of diffusing unit 15 is less than one-tenth of original beam diameter D , there will be a loss of less than 20 percent in the original beam energy density. Also, the refraction angle θ , corresponding to an index of refraction of 1.5 for keratin, into the tissue relative to collimated beam 24, when a gap exists between diffusively transmitting element 13 and clear transmitting element 17, will never exceed the critical angle of 42 degrees. At a refraction angle less than this critical value, possible additional scattering in tissue is minimized. Consequently light intensity within the tissue is preserved, therefore generally retaining the clinical efficacy, i.e. the ability to perform a surgical or cosmetic procedure, of the laser unit.

Just as superficial ablation 29 is formed in tissue 25 as a result of a high energy density beam in the 1.8 to 11.5 micrometer spectral range as shown in Fig. 5c, a similar ablation may be formed in tissue 25 with the use of diffusing unit 15, with the addition of Δd , as shown in Fig. 5d. A thin spacer (not shown) may be advantageously added in order to evacuate vapors or smoke that has been produced during the vaporization process. Such a spacer is e.g. U-shaped in vertical cross-transmission element, to allow for contact with a target at its lateral ends and for vapor evacuation along the gap formed by its central open region. For surgical procedures with which a very fast ablation rate is needed, e.g. 1 cm³/sec for a skin thickness of 0.1 cm, the spacer is necessarily relatively thick and the gap between the ablated tissue and the diffusing unit is relatively large, e.g. approximately 20-30 mm.

When an excessive amount of smoke is produced and the exit beam becomes diffracted before impinging on the tissue, it may be necessary to add a relay optics device (not shown), which regenerates the degraded exit beam between the diffusing unit and the tissue. An optical regenerator is

provided with an internal coating, such that a new and stronger beam with the same characteristics as the degraded beam is produced when the coating emits light energy when stimulated by the incoming photons of the degraded beam. Cylindrical or conical tubes internally coated with gold with an inlet diameter equal to the exit diameter of the diffusing unit are exemplary optical regenerators for this application. A small smoke evacuation port is preferably drilled in the wall of the tube.

When a long-wavelength laser, which does not focus on an eye retina and ranges from approximately 1345 nm to 10.6 microns, is employed, an diffusing unit may not be needed. To scatter the exit beam, an element may be externally attached to a surface which is in contact with the skin during a cosmetic or surgical procedure, so that the exit beam will diverge to a large extent and ensure eye safety from a distance of a few cm from a target, while the energy density is sufficiently high enough to allow for clinical efficacy. For example, a miniature 0.21 Joule/pulse Erbium laser, which produces a spot size of 1 mm² and generates an energy density of 2.1 J/cm², greater than the threshold for tissue ablation, will be safe to the eyes from a distance of 10 cm from a target if the beam has a divergence half angle of 45 degrees.

While the laser is an effective surgical tool when the diffusing unit is very close to the tissue surface, safety is ensured after the diffusing unit is repositioned so that it is disposed at a distance of a few millimeters, depending on the laser energy, from the tissue surface. As shown in Fig. 5e, the energy density of scattered beam 14 which impinges upon the surface of tissue 25 is much less than the energy density which results when the diffusing unit is proximate to the tissue surface.

The diffusing unit is adapted to induce random scattering despite any adverse external conditions encountered during the surgical procedure.

The most likely cause of a potential change in rate of scattering of the laser beam passing through diffusing unit 15 results from contact with tissue. Following a surgical procedure in which the diffusing unit contacts tissue, liquid residue 36, such as sebum, water and cooling gel, as shown in Fig. 6a, may accumulate on diffusively transmitting element 13. The refractive index of liquid residue 36 may be such that, in combination with the refractive index of diffusively transmitting element 13, refracted beam 38 approaches the pattern of collimated beam 24 that impinges on the diffusing unit.

To minimize the risk of injury which may exist if the refracted beam is nearly collimated, diffusively transmitting element 13 is mounted within diffusing unit 15, which is preferably hermetically sealed with sealing element 39 as shown in Fig. 6b, to prevent the accumulation of liquid residue on the former. Clear transmitting element 42 is attached to the distal end of diffusing unit 15 by adhesion and by means of a spacer (not shown), and is separated from diffusively transmitting element 13 by air gap 41. Clear transmitting element 42 and diffusively transmitting element 13 are mutually parallel, and both are perpendicular to the longitudinal axis of diffusing unit 15. When the air gap is less than a predetermined value, a corresponding increase in beam diameter due to scattering is limited, thereby ensuring a minimal effectiveness of the radiation carried by the laser beam for clinical applications. It would be appreciated that accumulation of liquid residue on clear transmitting element 42 will not compromise the inherent safety of a laser unit equipped with a diffusing unit. Since scattering occurs at diffusively transmitting element 13, and the combined index of refraction of air gap 41, clear transmitting element 42 and liquid residue is not sufficient to cause the scattered beam to be once again collimated, the inherent safety of the laser unit is preserved. The accumulation of liquid residue will not

affect the clinical efficacy of the laser unit since clear transmitting element 42 is held close to a target during a surgical procedure.

An additional advantage resulting from the separation of clear transmitting element 32 from diffusively transmitting element 13 relates to added safety. Even if clear transmitting element 42 is broken, diffusively transmitting element 13 will scatter the laser beam.

A diffusively transmitting element, adapted to achieve diffusing half angles greater than 45 degrees and as close as possible to an ideal transmitting diffuser, which generates a half angle of 60 degrees, may be produced in several ways:

- Sandblasting the surface of a plate of glass, sapphire, acrylic or polycarbonate with fine particles having a size ranging from 1 to 200 microns, depending of the wavelength of the laser beam, comprised of, by example, aluminum oxide;
- Sandblasting the surface of a mold plate with fine particles having a size ranging from 1 to 200 microns, depending on the wavelength of the laser beam, comprised of, by example, aluminum oxide and reproducing the contour of the newly formed mold plate surface by pressing hot acrylic, or other suitable material thereon;
- Etching the surface of a glass or sapphire plate by chemical means, such as with hydrogen fluoride;
- Etching the surface of a glass plate with a scanned focused CO₂ laser beam;
- Applying a thin sheet of light-diffusing polymer, such as a polycarbonate sheet, a light diffusing acrylic plate, Mylar high quality wax paper or graphical "Pergament Paper" to a glass plate;
- Generating a diffraction pattern on the surface of a glass or on a sheet of acrylic or polycarbonate by means of a holographic process to

thereby control the divergence angle through the diffraction pattern, which is preferably as large as a half angle of at least 40-45;

- Providing a randomly distributed array of thin fibers, arranged e.g. in the form of a conical fiber bundle light concentrator, such as that produced by Schott, Germany, whose aperture is provided with an exit half angle of greater than 40 degrees.

Figure 7 illustrates the scattering effect that is achieved by sandblasting. As shown in Fig. 7a, metallic plate 50 is bombarded with aluminum oxide particles 48, thereby creating a random distribution of craters 51, each of which having a different size. Liquid 52, which is sensitive to ultraviolet light, is spilled on metallic plate 50 in Fig. 7b and polymerized by ultraviolet radiation. After removal of plate 50, for reuse in the next production batch, transparent frosted plate 53 is produced, as shown in Fig. 7c covered on one side with a random distribution of convex lenses 55 of miniature size. Lenses 55, which have a very short focal length of approximately a few wavelengths, convert a collimated laser beam into a strongly divergent beam with a complete loss of coherence. It is possible to use a similar technique to produce a surface with convex or concave microlenses 57, as shown in Fig. 7d. Microlenses may be produced as well by pressing melted acrylic onto a multimicrolens mold, instead of using a UV curing technique.

As described above, an exit beam from a laser unit is randomly scattered by a diffusing unit. One type of a diffusing unit is a single wide angle diffuser as shown in Fig. 8a and comprises a diffusively transmitting element 781 which produces scattered light 782 from laser beam 780 having a wide diffusing angle of T . Another type of diffusing unit is shown in Fig. 8b, wherein wide angle diffusion is attained by using divergent optical element 783, and at least one diffuser 784 and refractive/reflective element 785. With this type of diffusing unit, a wide diffusing angle of T is

generated in three stages: optical element 783 produces wide angle divergent beam T_1 from laser beam 780, diffuser 784 produces a small diffusing angle of T_2 , and refractive/reflective element 785 expands angle T_2 to achieve wide diffusing angle T . Such a multi-component diffusing unit may achieve a wide diffusing angle with the use of elements of high thermal resistance and durability. It will be appreciated that refractive/reflective element 785 may not necessarily be distally disposed with respect to diffuser 784, and may be configured in any other way in order to achieve wide diffusing angle T .

Figure 9 illustrates another preferred embodiment of a diffusing unit, designated as numeral 200. Diffusing unit 200 is a wide angle diffusing unit, i.e. one that generates a scattering angle that approaches that of an ideal transmitting diffuser, yet is capable of enduring high power laser levels by using glass made of small angle diffusers. Such a diffusing unit is advantageously employed in those applications for which high energy densities are needed for clinical efficacy, and accordingly only a wide-angle scattering angle can ensure eye safety.

As depicted in Fig. 9a, optic fiber 201 is disposed adjacent to the proximate end of tapered light guide 202, such that light rays 203 that exit from fiber 201 with half angle divergence A impinge the inner wall of light guide 202. Rays 203 then are reflected from the inner wall of the light guide at an increasingly smaller reflection angle R . The inner wall is coated with a reflective coating so that reflection angle R will be less than the critical angle for total internal reflection. The tapering angle and the dimensions of the light guide as well as the distance of the fiber from the light guide are selected so that exit half angle C of diffused light 208 which propagates from distal end 204 of the light guide is at least 60 degrees. Also, the distance between fiber 201 and distal end 204 is selected so that the energy density of rays 207 emitted from fiber 202 to distal end 204

without any reflection from the light guide wall will be sufficiently low to be considered eye safe when scattered from small angle diffuser 205, e.g. 10 degrees, which induces a relatively small scattering angle and is proximately placed with respect to distal end 204 of the light guide. A small angle diffuser is advantageously selected due the availability of such diffusers, its high durability and capability to withstand a high energy density, as required for aesthetic and industrial applications. Small angle diffuser 205 increases the divergence of difused light 208, in addition to the divergence generated by tapered light guide 202.

In an exemplary diffusing unit, fiber 201 induces a half angle divergence of 25 degrees, the distance from fiber 201 to light guide 202 is 16 mm, the inner diameter of light guide 202 at its proximate end is 15 mm, the tapering angle of light guide 202 is 3 degrees, and the length of light guide 202 is 142 mm.

Diffusing unit 200 may also include a second light guide (not shown) which receives diffused light 208 from the distal end of light guide 202. This second light guide is sufficiently long so that diffused light 208, which propagates from small angle diffuser 205, will be emitted from the entire surface of the exit plane of the second light guide. The exit plane of the second light guide therefore functions as an extended diffused source. For example, a second light guide having a length of 50 mm and a small angle diffuser which induces a a scattering angle of 10 degrees will enable diffused light to span a diameter of greater than 5 mm at the exit of the second light guide.

As shown in Fig. 9b, diffusing unit 200 comprises array of microlenses 210, instead of an optic fiber as in Fig. 8a, which is disposed adjacent to the proximate end of tapered light guide 202. Array 210 is configured such that light rays 203 that exit therefrom with half angle divergence A

impinge the inner wall of light guide 202.

Figure 10 illustrates diffusing unit 700, which comprises another type of angular beam expander, namely one which comprises a set of concave and convex mirrors. Small angle fiber 701 from which light rays 703 exit with a small half angle divergence A, such as 5 degrees, is advantageously employed since diffuser unit 700 provides a high angular amplification.

As shown in Fig. 10a, half angle divergence A is selected so that a light ray 703 impinges on convex mirror 702 and is reflected therefrom to concave mirror 705. A ray 703 is further reflected from mirror 705 at an angle that enables it to impinge upon, and be scattered by, diffusively transmitting element 710, which is affixed to concave mirror 705. In Fig. 10b, diffuser unit 700 is additionally provided with light guide 715. The light which exits from diffusively transmitting element 710 is received by light guide 715 and is reflected within its inner wall, resulting in wide angle diffusing from the entire exit surface of light guide 715. Light guide 715 therefore functions as an ideal extended diffused light source.

Fig. 11 illustrates a diffuser unit in which two 40-45 degrees holographic diffusers 220 and 221 are attached to light guides 222 and 223, respectively. Each holographic diffuser induces a half angle divergence of approximately 45-50 degrees. In order to increase the divergence, two holographic diffusers are used. Light rays 218 propagating from a monochromatic light source are scattered by diffuser 220 to a half angle of D and then are reflected within the inner wall of light guide 222. The scattered light rays are further scattered by diffuser 221 to a half angle of E, are reflected within light guide 223, and exit the diffuser unit at a half angle of F, which approaches 60 degree, the value corresponding to an ideal transmitting diffuser. The light guides are chilled so that the holographic diffusers, which are usually made from plastic material, will

also be chilled so that they will be able to withstand the high thermal stress imposed by a high power laser beam. Each light guide may be solid or hollow, and may be made from glass, sapphire, a liquid dielectric, or plastic.

Figure 12 illustrates another preferred embodiment of the invention in which diffuser unit 300 comprises two distinct diffusers 301 and 302, wherein at least one is axially displaceable. Fig. 12a illustrates diffuser unit 300 in an active position, such that diffusers 301 and 302 are essentially in contact with each other. When in an active position, diffusers 301 and 302 act as a singular randomly scattering diffuser, since substantially all of the monochromatic light 305 that impinges on diffuser 301 is transmitted to diffuser 302. Although the energy density needed for performing an efficacious treatment with monochromatic light 305 is minimally affected, a slight increase of the laser energy can compensate for any energy density losses. Fig. 12b illustrates diffuser unit 300 in an inactive position, such that diffusers 301 and 302 are separated from each other by a distance L , which is sufficiently long to ensure that the radiance of the scattered light which exits diffuser 301 and is additionally scattered by diffuser 302 is below a level that is safe to one's eyes.

As shown, diffuser 301 is axially displaceable by means of a plurality of springs 308 that connect diffuser mount 301a to diffuser mount 302a. When lever 315, which is connected to diffuser mount 301a, is depressed springs 308 are compressed and diffuser 301 becomes substantially in contact with diffuser 302, as shown in Fig. 12a. Distal end 317 of handpiece 303 is then brought in contact with a skin location to be treated by monochromatic light 305 having a high energy density and a high radiance. Upon completion of a desired surgical or cosmetic procedure, lever 315 is released and springs 308 are biased to separate diffuser 301 from diffuser 302 by a distance of L , as shown in Fig. 12b, whereby the

radiance of the scattered light is below a safe level. It will be appreciated that any other means well known to those skilled in the art for axially displacing one or more of the diffusers may be used.

Fig. 13 illustrates an embodiment of the present invention by which tissue, having a larger surface area than the area of the beam impinging thereon, may be treated without overexposure to a laser beam. In prior art systems using a scanner, the treatment beam is quickly displaced in a programmable fashion from one location to another on the tissue to be treated. Although this method provides rapid and reliable treatment, there is a significant risk, however, that the laser beam is liable to be aimed at eyes, skin or flammable materials located in the vicinity of the laser unit.

The diffusing unit generally designated by 60 is shown. In this embodiment the diffusing unit is rigidly attached to delivery system 61, which is provided with a scanner. Diffusively transmitting element 63 is formed with a plurality of visible targets 66 and is placed close to the skin, facing the distal end of delivery system 61. Diffusing unit 60 is preferably provided with a clear transmitting element, as described hereinabove. Coherent collimated or convergent exit beam 64 is directed via a plurality of repositionable reflectors 65 to a predetermined target 66 graphically indicated on diffusively transmitting element 63. The beam that impinges upon a predetermined target 66 is randomly scattered and converted into non-coherent beam 67 whose energy density is essentially similar to that of exit beam 64. Reflectors 65 are controllably repositionable by means of a scanner, whereby they may be displaced from one position and angular disposition to another, so as to accurately direct exit beam 64 to another target 66. The sequence of which target is to receive exit beam 64 after a selected target is programmable and is preferably semi-random to reduce pain which may be felt resulting from the treatment of two adjacent targets, with the time increment between two doses of laser treatment

being less than a preferred value. A programmable sequence precludes on one hand the chance of a target not to receive an exit beam at all, and on the other hand precludes the chance of not to be inadvertently exposed twice to the exit beam. With the usage of diffusing unit 60, small-diameter beams, e.g. 0.1-7.0 mm, may be advantageously employed to treat a tissue having an area of 16 cm². Similarly, a scanner may be employed for any other feasible wide-area diffusing unit, such as an array of diffusers/light guides incorporating those units illustrated in Figures 9-12, whereby an exit laser beam may be directed to each of the diffusers/light guides. Such an array may consist of 9 diffuser/light guides, each having a 3-mm diameter, to cover an area of 81 mm². Scanning may also be achieved by laterally moving an angular expander over the diffuser/ light guide array.

Figure 14 illustrates another preferred embodiment of the invention in which a diffusing unit is not used, but rather a diverging optical element is employed to produce an exit beam having radiance, or alternatively, energy density, depending on the wavelength, below a safe level.

As shown in Fig. 14a, diverging optical element 741 is placed in diverging unit 748, which is attached to the distal end of the laser unit by any means depicted hereinabove in Figure 2. Divergent element 741, which is provided with a relatively short focal length, focuses input beam 740 at point F. The beam diverges at a point distally located with respect to point F, as well known to those skilled in the art, and produces divergent beam 742 having a divergent angle of H, a cross section 743 at a plane coplanar with distal end 744 of diverging unit 748 and a cross section 752 at a plane coplanar with shield 750. When divergent beam 742 has a cross sectional dimension at least equal to cross section 752, its radiance is less than an eye safe level.

Pulsed laser radiation in the wavelength range of 1400 nm to 13 microns, according to the ANSI Z 136.1 standard, is considered eye safe if the Accessible Energy Limit (AEL) at the ocular plane is less than a value of $0.56 * t^{1/4}$ J/cm², where t is the pulse duration in seconds. For example, a typical pulse duration ranging from 1 to 100 msec is associated with an AEL ranging from 0.1 to 0.3 J/cm², respectively. Accordingly, diverging unit 748 is provided with at least one shield 750, each of which prevents one's head from entering a zone of the divergent beam at which the energy density is greater than the AEL. Shield 750 is connected to tube 746 of diverging unit 748 by means of rigid member 747, and cross member 749. The length of cross member 749 and the degree of angular divergence H is selected to ensure that the energy density distal to shield 750 is less than the AEL. Normally, cross member 747 is unyielding to head pressure, thereby ensuring eye safety. However, when a lever is actuated, for example, cross member 747 is opened and a spring (not shown), which is normally in a relaxed state and connected to both rigid member 747 and cross member 749, becomes tensed and allows the shield to be proximately displaced. When shield 750 is proximately displaced, distal end 744 of diverging unit 748 may be in contact with a target skin location and cross section 743 of beam 742 having a sufficiently high energy density for a desired application may be utilized. For example, diverging unit 748 is suitable for those applications by which a laser beam is greatly absorbed by water.

Fig. 14b illustrates diverging unit 950, which comprises array 991 of focusing lenslets each of which has a diameter of e.g. 0.7 mm, array 992 of lenses each of which is provided with reflective coating 993 on its distal side, and a plurality of convex reflectors 995 attached to transparent plate 994. Rays 990 from a collimated laser beam are focused by lenslets 991 and transmitted through non-reflective area 999 formed on the distal side of each lens 992. The location of each non-reflective area 999 is selected so

that a focused ray propagating therethrough will impinge upon a corresponding reflector 995 at such a reflecting angle such that it will be reflected therefrom and strike a corresponding reflective coating 993, from which it is again reflected and propagates through transparent plate 994. Most rays, such as ray 996 then exit plate 994. However, some rays, such as ray 989, strike a transversal side 997 of plate 994, which is provided with a reflective coating and causes these rays to exit plate 994. Plate 994 accordingly functions as a light guide when transversally reflecting light rays strike a side 997. The length, i.e. the distance between sides 997, of plate 994 is substantially equal to the length of array 991, and therefore the energy density of an input beam is preserved at the exit of plate 994. In order to comply with the requirements of the aforementioned standards, namely to achieve a safe radiance level with a lens having a diameter of 0.7 mm and producing a divergent half angle of 60 degrees, a lenslet 991 with a focal length of 3 mm may be used to achieve a uniform radiance at a solid angle of approximately Π steradians.

The distal end of plate 994 may be etched to further diffuse the divergent light exiting therefrom, so that the distal end may function as an extended diffused light source. If desired, the transparent plate may be substituted by a light guide.

In summation, the present invention incorporates four groups of units which cause a monochromatic light to diverge at a sufficiently wide angle so that the radiance of an exit beam is eye safe:

- 1) A diverging unit provided with a single diverging optical element;
- 2) A multi-component diverging unit provided with reflective and refractive optical elements, and without any diffusers;
- 3) A diffusing unit provided with a single thin diffusively transmitting element; and
- 4) A multi-component diffusing unit, whereby a wide divergent,

diffusing angle is achieved by using a high thermally resistant refractive/reflective optical component, as well as at least one thermally resistant low angle diffuser.

When a multi-component diffusing or diverging unit is employed, a relatively simple eye safety monitoring device can be used. Due to the high thermal durability of the selected multi-component unit, the radiance homogeneity is essentially preserved from the proximate end to the distal end thereof. Consequently, limited sampling of the radiance level is required, and an expensive monitoring device is rendered unnecessary. Another advantage of a multi-component unit is that monochromatic light reflected from the skin returns to the corresponding unit via a light guide with respect to a diffusing unit and via a transparent plate with respect to a diverging unit, preventing an adverse effect to the skin if reflected monochromatic light were to return thereto.

Figure 15 illustrates another preferred embodiment of the invention in which a diffusing unit is provided with a skin cooling system. Transparent skin cooling devices are often used in conjunction with skin laser treatments. However they do not scatter laser light and do not reduce the risks associated with exposure to a laser beam. Figs. 13a-d illustrate prior art skin coolers. In Figs. 15a and 15b transparent lenses or plates 80 are in contact with tissue 79. Cooling liquid 81, which flows through conduit 83, conducts heat from the heated skin to a cooler. Treatment laser beam 82 propagates without being scattered through the cooling device and penetrates the skin. In Fig. 15c gaseous coolant 84 is used. In Fig. 15d, highly conductive plate 86 is in contact with tissue 79 and chilled by thermoelectric cooler 85.

As shown in Fig. 15e, diffusing unit 75 comprises diffusively transmitting element 74, clear transmitting element 70 and conduit 71 formed

therebetween. Conduit 71 is filled with a low temperature gas or liquid of approximately 4°C, which enters conduit 71 through opening 72 and exits at opening 73. The cooling fluid preferably flows through a cooler (not shown). Diffusing unit 75 is positioned in contact with the skin, for treatment and cooling thereof. Clear transmitting element 70 is preferably produced from a material with a high thermal conductivity such as sapphire, in order to maximize cooling of the epidermis. Diffusively transmitting element 74 is disposed such that its proximal face is frosted side and its distal face is planar, facing conduit 71. In Fig. 15f, the diffusing unit comprises diffusively transmitting element 74 made from sapphire, which is chilled at its lateral sides 75 by thermoelectric cooler 76. The proximal side of 74 is frosted and the smooth distal side faces the skin. The parameters of the flowing fluid and of the cooler are similar, by example, to the Cryo 5 skin chiller produced by Zimmer, California, USA. It will be appreciated that any of the skin cooling means illustrated in Figs. 15d-f may be used to cool skin which is heated as a result of the impingement of monochromatic light thereon even though a diffusively transmitting element is not used.

The eye safety when exposed to the exit beam of a diffusing or diverging unit is significantly improved relative to prior art devices.

Parameters for eye safety analysis are presented in "Laser Safety Handbook," Mallow and Chabot, 1978 in which the standard ANSI Z 136.1 is cited. A laser beam which is reflected from a light diffusing surface is categorized as an extended diffused source if it may be viewed at a direct viewing angle A , greater than a minimum angle A_{min} , with respect to a direction perpendicular to the source of the laser beam. If a reflected beam may not be viewed at angle A , it is categorized as an intrabeam viewing source. Since a reflected beam is more collimated when viewed at a

distance, viewing conditions are intrabeam if the distance R from the source of the laser is greater than a distance R_{\max} .

Another significant parameter is the maximum permitted radiance, normally referred to as Accessible Energy Limit (AEL) while staring at a diffusing surface which completely reflects a laser beam. AEL depends on the energy density, exposure duration, and wavelength of the laser beam, as well as the solid angle into which the laser beam is diffused. The safety level of a laser unit is evaluated by comparing the AEL to the actual radiance (AR) of the laser beam. Staring at the exit of a diffusing unit according to the present invention is equivalent to staring at a reflecting extended diffuser with 100% reflectivity. The AEL for visible and near infrared radiation exiting a diffusing unit for which protective eyeglasses are unnecessary based on an extended diffuser source is defined by ANSI Z 136.1, as $10 \cdot k_1 \cdot k_2 \cdot (t^{1/3})$ J/cm²/sr, where t is in seconds and $k_1 = k_2 = 1$ for a wavelength of 400-700 nm, $k_1 = 1.25$ and $k_2 = 1$ at 750 nm, $k_1 = 1.6$ and $k_2 = 1$ at 810 nm, $k_1 = 3$ and $k_2 = 1$ at 940 nm and $k_1 = 5$ and $k_2 = 1$ at a wavelength of 1060 to 1400 nm. The safety limit set by ISO 15004 : 1997 E for pulsed radiation is 14 J/cm²/sr.

The actual radiance (AR) is the actual energy per cm² per steradian emitted from a diffusing unit. The ratio between AEL and AR indicates the safety level of the laser unit employing a diffusing unit, according to the present invention. A ratio less than 1 is essentially unsafe. A ratio between 1.0 and 5 is similar to that of high intensity flashlight sources used in professional photography and intense pulsed light sources used in aesthetic treatments, and is much safer than prior art laser sources. Prior art laser sources which do not incorporate a diffusing unit have a ratio which is several orders of magnitudes less than 1.

Table I below presents a comparison in terms of eye safety between the exit beam of monochromatic light after being scattered by a diffusing unit into a solid angle of 3.14 sr, which is equivalent to that attained by an ideal transmitting diffuser, according to the present invention. The parameters for a non-coherent diode-based laser unit are based on one produced by Dornier Germany. The parameters for a non-coherent Alexandrite-based laser unit are based on one produced by Sharplan/ESC (Epitouch). The parameters for a non-coherent Nd:YAG-based laser unit intended for hair removal are based on one produced by Altus, USA. The parameters for a non-coherent Nd:YAG-based laser unit intended for photo-rejuvenation are based on one produced by Cooltouch, USA. The parameters for a non-coherent dye-based laser unit are based on one produced by ICN (Nlight). The parameters for an intense pulsed light laser unit are based on one produced by ESC. The AEL for a particular wavelength and pulse duration is based on the aforementioned ANSI Z 136.1 standard.

Table I

System type	Non coherent Diode based	Non coherent Alexandrite based	Non coherent Nd:YAG based	Non coherent Nd:YAG based	Non coherent Dye based	Intense Pulsed Light	CW Diode 60 degrees diffuser
Application	Hair removal	Hair removal	Hair removal	Photo-rejuvenation	Photo-rejuvenation	Hair removal	Tooth whitening
Parameters							
Wavelength	940 nm	755 nm	1064 nm	1320 nm	585 nm	645-900 nm	980 nm
Energy	6 J	10 J	11.3 J	7 J	0.6 J	90 J	1.5 J
Pulse duration	50 msec	40 msec	60 msec	60 msec	0.5 msec	40 msec	1 sec
Spot size	5 mm	7 mm	6 mm	6 mm	5 mm	10X30 mm ²	5X5 mm ²
Energy density	30 J/cm ²	25 J/cm ²	40 J/cm ²	25 J/cm ²	3 J/cm ²	30 J/cm ²	6 J/cm ²
Extended view parameters							
A min							
R max	8 mrad 0.4 m	3.5 mrad 2 m	4 mrad 2 m	4 mrad 2 m	2.5 mrad 1.3 m	5 mrad 4 m	15 mrad 0.33 m
Eye safety Parameters							
AEL/sr	11 J/cm ² /sr	4.3 J/cm ² /sr	19.5 J/cm ² /sr	20 J/cm ² /sr	0.79 J/cm ² /sr	3.4 J/cm ² /sr	35 J/cm ² /sr
AR/sr	9.6 J/cm ² /sr	8 J/cm ² /sr	12.7 J/cm ² /sr	8 J/cm ² /sr	0.79 J/cm ² /sr	9.5 J/cm ² /sr	8 J/cm ² /sr
Eye safety Figure of merit AEL/AR	1.14	0.53	1.54	2.5	1	0.35	4.1

The table shows that the exit beam according to the present invention is essentially as eye-safe, or safer than, broad band non-coherent intense pulsed light sources, such as those used for professional photography or those used for cosmetic surgery. The scattered monochromatic light, for most of the light sources, does not necessitate protective eyeglasses and is safer than an accidental glance into the sun for a fraction of a second. Although the ratio for the Alexandrite and Intense Pulsed Light sources is less than 1 and protective eyeglasses must be worn, the required optical attenuation for these light sources is less than 3, much less than the required optical attenuation with the use of a conventional monochromatic light source not provided with a diffusing unit, which is on the order of 10^4 - 10^7 . It will be appreciated that a similar level of eye safety for laser units utilizing a diffusing unit may be achieved with a very wide scattering angle, approaching a half angle of 60 degrees or a solid angle of π steradians. Small angle scattering may result in a different level of eye safety when operated at an energy density suitable for aesthetic treatments; nevertheless, such a scattered exit beam is much safer than the exit beam of a conventional coherent laser unit.

The radiance of the light emitted by a diffusing unit can be measured to verify that it is in compliance with the appropriate standards for laser eye safety. In one embodiment, a converted laser utilizing a diffusing unit in accordance with the present invention is provided with an eye safety measurement device. Such a device may be an energy meter such as that produced by Ophir, USA or an array of light detectors 805 as depicted in Fig. 16. The eye safety measurement device is provided with control circuitry which is in communication with the operating system of the laser unit, so that, as a result of a mishap, a warning is issued indicating that protective eyeglasses are required if the measured radiance of a scattered

laser beam is greater than a predetermined safe value. Alternatively, the control circuitry may discontinue operation of the laser unit if the measured radiance of a scattered laser beam is greater than a predetermined safe value.

Fig. 16 illustrates an exemplary eye safety measurement device, designated as numeral 800. Device 800 is operative to measure the radiance of scattered light 810, which is scattered by means of diffusing unit 15 attached to distal end 809 of laser unit handpiece 801. Device 800 is provided with an array of light detectors 806, e.g. complementary metal oxide semiconductor (CMOS) detectors which provide light imaging, at distal end 805 thereof, on which scattered light 810 impinges after passing through aperture 808 of diameter Q_0 and lens 807. After distal end 809 is inserted into a complementary opening formed within device 800 until contacting annular abutment plate 804 perpendicular to outer wall 803 of device 800, the laser unit is fired. For purposes of clarity, light which propagates thorough segment Q_1 of diffusing unit 15 impinges on segment Q_2 of detector array 806. The radiance of scattered light 810 therefore is determined by dividing the amount of energy sensed by detectors 806 by diameter Q_0 of aperture 808 and by the solid angle characteristic of the detector structure. For example, the distance D between abutment plate 804 and aperture 808 is 200 mm, segment Q_1 of the diffusing element 15 is 0.7 mm, and diameter Q_0 of the aperture is 7 mm, to comply with the regulations set forth in ANSI Z 136 .1.

Figure 17 illustrates another embodiment of the invention, wherein eye safety in the vicinity of a laser unit that emits an infrared beam or other invisible radiation is increased by adding a flashing device to the laser system to cause one's eyes to blink during the propagation of the laser beam.

Fig. 17a illustrates distal end 960 of a laser unit, which emits light 955 generated therefrom, preferably being scattered monochromatic light when a diffusing unit is employed. To prevent damage to eye 962 of a bystander located in the vicinity of the laser unit, flashing device 961 is added to distal end 960. Flashing device 961 generates a short visible light flash a fraction of a second prior to the firing of a laser beam.

As shown in Fig. 17b, activation of the laser unit initiates an electrical pulse 963 at time t_0 , which triggers a timer circuit (not shown). The timing circuit is adapted to generate and transmit pulse 964 at time t_1 to flashing device 961, to produce a flash is sensed by eye 962. Flashing device 961 may be a well known flashing means associated with cameras or may utilize diodes, or any other feasible means to produce an instantaneous flash. After a predetermined period of time, the timing circuit transmits a pulse to the control system of the laser unit to fire a laser beam at time t_2 . This predetermined period of time, namely the difference between t_2 and t_1 , is approximately 0.25 seconds, equal to the reaction time of uncontrolled blinking as a response to light, and is preferably no more than 0.20 seconds. A flashing device 961 may be added to any source of monochromatic light, such as any type of laser or IPL sources, whether producing visible or invisible light.

Fig. 17c illustrates another application of flashing device 961. By generating a flash with device 961 and determining whether detector 975 senses light retroreflected from eye 962, a microprocessor (not shown) in communication with a control circuit (not shown) and with detector 975, e.g. a photodetector, can determine that eye 962 is in danger of being injured from the imminent firing of a laser beam from the laser unit. The choroid layer of the retina diffusely reflects light source 973 that impinges

thereon from the previously generated flash, and the optics of eye 962 re-image, or retroreflect, the light back to flashing device 961. Retroreflected beam 974 is reflected from beam splitter 970 through a lens (not shown) onto 975. Two additional adjacent detectors (not shown) detect light reflected from other areas in the room in which the laser unit is disposed. If the signal generated by detector 975 has a much larger amplitude than the signals generated by the additional detectors, the microprocessor determines that eye 962 is in firing range of a laser beam. The control circuit of flashing device 961 then sends a disabling signal to the control system of the laser unit to thereby prevent firing of a laser unit. When detector 975 is used to detect a retroflected beam, and a flash is generated within the predetermined time before the firing of a laser beam, as illustrated in Fig. 17b, in order to cause uncontrollable blinking of the eye during propagation of the beam, the laser unit is inherently fail-safe. That is to say, even if the eye does not blink, detector 975 will determine that eye 962 is in firing range of a laser beam and the laser unit will cease operation.

As can be seen from the above description, a diffusing/diverging unit of the present invention, which is mounted to the exit aperture of a conventional laser unit, induces the exit beam to be divergent/ and or scattered at a wide angle. As a result the exit beam is not injurious to the eyes and skin of observers, as well as to objects located in the vicinity of the target. Nevertheless, the exit beam generally retains a similar level of energy density as the beam generated from the exit aperture when the diffusing unit is very close or essentially in contact with the target, and is therefore capable of performing various types of treatment, both for cosmetic surgery and for industrial applications. Protective eyeglasses are generally not needed, and if they are needed, conventional sunglasses would be the

only requirement, thereby allowing work in an aesthetic clinic to be less cumbersome.

Example 1

An experiment was performed to demonstrate the operating principles of the present invention in which transparent light diffusing adhesive "Magic Tape," manufactured by 3M, having a thickness of 100 microns was attached to the distal end of an Alexandrite laser unit having a diameter of 8 mm. The energy level of the laser beam is 11 J/pulse. The laser beam was directed to the white (rear) side of a black developed photographic paper having a thickness of 300 microns. For comparison, the laser beam was also directed to the photographic paper without the use of the adhesive tape.

The ablation of the black paper after the beam had propagated and scattered through the white paper provides a visual simulation of the capability of the laser beam to penetrate transparent light-scattering skin in order to treat black hair follicles (or any other type of lesion) under the skin.

The energy of the laser beam transmitted through the adhesive tape, which caused the laser beam to scatter, was measured by directing the beam to an energy meter located at a distance of 1 mm from the distal end of the laser unit. The energy of the scattered laser beam dropped from 11 to 10 J. The results of this experiment indicate that the diffusively transmitting element did not absorb a significant amount of energy, since a loss of 10% is expected in any case due to Fresnel reflection.

When the laser beam was directed to the white (rear) side of a developed photographic plate at a distance of 1 mm, an ablation of the black color on

the opposite side of the photographic paper resulted. There was no difference in the results between usage of light diffusing tape or not. This experiment demonstrates that the performance of a non-coherent Alexandrite laser beam, according to the present invention, at a distance of 1 mm is essentially equal to the corresponding coherent laser beam.

When the laser beam was directed, without the addition of light diffusing tape, at the photographic paper from a distance of at least 8 mm, an ablation resulted that is identical to that which was generated from a short distance of 1 mm. However, when light diffusing tape was applied to the exit aperture of the laser unit from a distance of at least 8 mm, the scattered beam did not result in an ablation. Accordingly, the present invention allows for a high level of safety and lack of damage to bodily tissue when disposed at a relatively large distance therefrom.

Example 2

In a second experiment a long pulse Alexandrite laser unit having a wavelength of 755 nm, pulse duration of 40 msec, and having an energy density of 25 J/cm² was used for hair removal. A diffusing unit with an ultra-densely woven polymer-based diffuser having a half angle of 15 degree produced by Barkan or a holographic diffuser produced by Physical Optics Corporation (USA) having a half angle of 40 degrees was employed. The diffusers were used in a one-time basis. Chilling gel was applied between the diffuser and the skin.

Each pulse of a laser beam scattered by a diffusing unit formed a spot of 5.5 mm on various skin locations including arms, bikini lines and armpits of 10 patients. Full hair removal was noticeable immediately after the firing of the laser beam. Each spot was compared to a control area with an identical diameter formed by an unscattered laser beam generated by the

same laser unit with similar parameters, and similar results were achieved. Hair did not return to those spots for a period of one month.

Example 3

A long pulse Alexandrite laser unit having a wavelength of 755 nm, pulse duration of 40 msec, and having an energy level of 1-20 J is suitable for hair removal.

The diameter of the diffusing unit is 7 mm, and its scattering half angle is 60 degrees. A diffusing unit comprising a diffuser with a small scattering angle, a highly divergent lens and a light guide is added to the distal end of the laser unit.

The prior art energy density of 10-50 J/cm² is not significantly reduced with the employment of a diffusing unit. The laser unit operates at 25 J/cm² and generates a radiance of 8 J/cm²/sr. Since the acceptable radiance limit according to ANSI Z 136.1 is 4.3 J/cm²/sr, bystanders are required to use protective eyeglasses with 50% optical attenuation, an attenuation similar to that of sunglasses and an order of 100,000 less than typical protective eyeglasses worn during operation of a laser unit. For a larger target area, a scanner such as the Epitouch model manufactured by Lumenis may be used.

A diffusing unit having a diameter of up to 7 mm is particularly suitable for lower energy lasers, which are relatively small, remove hair at a slower speed from limited area and are inexpensive. An application of such a laser, when employed with a diffusing unit, includes the removal of eyebrows.

Example 4

A pulsed Nd:YAG laser unit such as one produced by Altus (USA) or Deka (Italy) having a wavelength of 1064 nm, pulse duration of 100 msec, and having an energy level of 0.5-60 J is suitable for hair removal at an energy density ranging from 35-60 J/cm².

A diverging unit with an array of focusing lenslets, an array of lenses provided with reflective coating on its distal side, and a plurality of convex reflectors attached to a transparent plate is used, such that the diverging half angle is close to 60 degrees. When a laser beam having an energy density of 40 J/cm² is generated, a radiance of 12.7 J/cm²/sr at the exit of the diverging unit is induced, approximately half of the maximal permitted radiance according to ANSI Z 136.1.

Example 5

A long pulse diode laser unit having a wavelength ranging from 810-830 nm, or of 910 nm or 940 nm pulse duration ranging from 1-200 msec, and having an energy level of 0.5-30 J is suitable for hair removal at an energy density ranging from 20 -50 J/cm².

The diameter of the treated area, or spot size, ranges from 1-20 mm. The diffusively transmitting element is preferably made from fused silica, sapphire, , or is a holographic diffuser used in conjunction with a light guide or with any other diffusing unit described hereinabove. The scattering half angle is close to 60 degrees. A scanner may be integrated with the diffusing unit. The delivery system to which the diffusing unit is attached may be a conical light guide, such as that manufactured by Coherent or Lumenis, a guide tube produced e.g. by Diomed or a scanner produced e.g. by Assa. With a diffusing unit having a diameter of 5 mm and a laser beam generated with an energy density of 20 J/cm² and a pulse

duration of 100 msec, the radiance at the exit of the diffusing unit is 9.6 J/cm²/sr, lower than the maximal permitted radiance value of 11.0 J/cm²/sr.

Example 6

A miniature diode laser unit for home use operating at a wavelength of approximately 810 nm, or 940 nm, such as one produced by Dornier, Germany, and having a power level of 4 W is suitable for hair removal. The invention converts a continuous working diode laser unit, which is in a high safety class and usually limits operation to the medical staff, into a lower safety class, similar to non-coherent lamps of the same power level.

The diffusing unit utilizes an angular beam expander with a convex reflector, a concave reflector having an inner diameter of 16 mm, a 10-degree glass diffuser, and a light guide having a length of 20 mm and an inner diameter of 2 mm. The diameter of the treated area, or spot size, is approximately 2 mm. The energy density at the exit of the light guide is 30 J/cm² and the radiance thereat is approximately 10 J/cm²/sr. A scanner may be integrated with the diffusing unit. The diode laser may also be used without a scanner, in which case the laser will be pulsed for a duration of approximately 300 msec.

Example 7

A Ruby laser unit having a wavelength of 694 nm, pulse duration ranging from 0.5-30 msec, and having an energy level of 0.2-20 J is suitable for hair removal.

The diameter of the treated area, or spot size, ranges from 1-20 mm. The larger spot sizes can be generated by Ruby lasers manufactured by Palomar, ESC and Carl Basel, which provide an energy density ranging

from 10-50 J/cm². The smaller spot sizes can be generated by inexpensive low energy lasers, which are suitable for non-medical personnel. A multi-component diffusing or diverging unit may be used. The laser unit is much safer than a conventional laser unit

A scanner, such as manufactured by Assa of Denmark or by ESC, may be used to displace a reflected collimated beam from one aperture to another formed within the diffusing or diverging unit. The scanning rate is variable, and the dwelling time at each location ranges from 20-300 msec.

Example 8

High risk laser units, such as Nd:YAG having a wavelength of 1.32 microns and manufactured by Cooltouch with a pulse duration of up to 40 msec, a dye laser having a wavelength of 585 nm and manufactured by N-Light/SLS/ICN, or a Nd:Glass laser having a wavelength of 1.55 microns with a pulse duration of 30 millisecond may be used for non-ablative skin rejuvenation. This application is aimed at the treatment of rosacea, mild pigmented lesions, reduction of pore sizes in facial skin and mild improvement of fine wrinkles, without affecting the epidermis. The advantage of these lasers for non-ablative skin rejuvenation is related to the short learning curve and more predicted results due to the small number of treatment parameters associated with the single wavelength. By implementing a diffusing unit, the laser unit becomes safe and may be operated by non-medical personnel.

An N-Light laser unit is initially operated at an energy density of 2.5 J/cm² for collagen contraction. The addition of a diffusing unit makes the laser unit as safe as an IPL. The addition of a multi-component diffusing or diverging unit with a divergent half angle of 60 degrees and an exit

diameter of 5 mm results in a radiance level of $0.79 \text{ J/cm}^2/\text{sr}$, which is equal to maximal accepted limit.

A laser beam may be generated with a considerably less expensive laser unit, having an energy level ranging from 0.5-3 J and a slow repetition rate such as 1 pps, and generating a spot size ranging from 2-4 mm. In the case of wrinkle removal, the operator may follow the shape of the wrinkles with a small beam size. Such a non-coherent laser beam having a beam size of 2-4 mm is particularly suitable for aestheticians. Using a diffusing unit depicted in Fig. 10b with a 10 degree diffuser and a light guide having a length of 30 mm results in a laser unit with a radiance of approximately $0.5 \text{ J/cm}^2/\text{sr}$.

Example 9

A pulsed Nd:YAG laser unit having a wavelength of 1064 nm and manufactured by ESC and having an energy level of 0.5-60 J is suitable for treatment of vascular lesions. The pulse duration ranges from 1-200 msec, depending on the size of the vessels to be coagulated (300 microns to 2 mm) and the depth thereof below the surface of the skin. A LICAF (Lithium Calcium Fluoride) laser unit at a wavelength of 940 nm may also be advantageously used for this application, and its associated laser beam is better absorbed by blood than the Nd:YAG or Dye laser. A Dye laser at a wavelength of 585 nm and manufactured by Candela may be used to treat vessels located at a low depth below the skin surface, such as those observed in port wine stain, telangiectasia and spider veins.

The diameter of the treated area, or spot size, ranges from 1-10 mm, depending on the energy level. A multi-component diffusing or diverging unit is used, due to the relatively high energy density of greater than 90

J/cm² needed for the treatment of deep vascular lesions. A scanner may be integrated with the diffusing unit.

Example 10

Q-Switch laser units having a pulse duration ranging from 10-100 nsec and having an energy density of 0.2-10 J/cm² is suitable for removal of pigmented spots, mostly on the face and hands, as well as removal of a tattoos. A Q-switched Ruby laser as manufactured by ESC or Spectrum, a Q-Switch Alexandrite laser manufactured by Combio, and a Q-Switch Nd:YAG laser may be used for such an application.

The diameter of the treated area, or spot size, ranges from 1-10 mm, depending on the energy level. A diffusing unit utilizing two diffusively transmitting elements is used, wherein one is fixed while the other is axially displaceable such that both elements are essentially in contact with each other in an active position, e.g. a gap of approximately 0.2 mm when a laser beam is fired. The gap between the two elements is approximately 15 cm when the laser is not fired. The diameter of the diffusing unit is 6 mm. Each diffusively transmitting element is preferably made from glass, sapphire or polymer.

The addition of such a diffusing unit with an axially displaceable diffuser to the aforementioned laser units is instrumental in rendering pigmented lesion and tattoo removal to be a considerably less risky procedure. Tattoo removal is achieved only by means of a laser beam, and is not attainable with intense pulse light sources.

The removal of pigmented lesions may also be performed with the use of an Erbium laser unit operated at a wavelength of 3 microns. Most pigmentation originates from the epidermis, and such a laser beam

penetrates only a few microns into the skin. With implementation of a diffusing unit, this procedure may not necessarily be performed by medical specialists. Aestheticians will be able to treat a large number of patients, particularly since an Erbium laser is relatively inexpensive.

Another application of the present invention involves the field of dentistry, and relates to the treatment of pigmented lesions found on the gums. Q-switched as well as Erbium lasers may be used for this application.

Example 11

A CO₂ laser may be used for wrinkle removal. In prior art devices, such a laser is used in two ways in order to remove wrinkles: by ablation of a thin layer of tissue at an energy density greater than 5 J/cm² with a Coherent Ultrapulse, ESC Silktouch, or Nidek Co₂ laser and scanner for a duration less than 1 msec; or by non-ablative heating of collagen in the skin for lower energy densities, such as at 3 W, which may be achieved by operation of a continuously working ESC derma-K laser for 50 msec on a spot having a diameter of 3 mm.

With implementation of the present invention in which a multi-component diffusing or diverging unit is attached to a CO₂ laser, a laser beam having a wavelength of 10.6 microns may be generated. As opposed to other far infrared sources whose thermal and spectrally broad bandwidth involves less control of penetration depth, the interaction of a laser beam with tissue according to the present invention is highly controllable and its duration can be very short.

The diffusing and diverging units are preferably made from a lenslet that is transparent to a CO₂ laser beam such as ZnSe or NaCL. The diameter of the diffusing unit ranges from 1-10 mm. The divergent angle is greater

than the minimal acceptable value so as to produce a radiance level at the exit beam that is essentially eye safe.

During ablation, a clear transmitting element of the diffusing unit is separated from the tissue to be treated by a thin spacer having a thickness of approximately 1 mm to allow for the evacuation of vapors or smoke produced during the vaporization process.

Similarly an Erbium laser unit operating at an energy density above 2 J/cm² and generating a laser beam greater than 3 microns may be used for wrinkle removal. Ablation is shallower than attained with a CO₂ laser and application of an Erbium laser unit can be extended to tatto or permanent make up removal.

Example 12

A Nd:YAG or oyer laser unit may be used for treatment of herpes. A diode laser with selective absorption of Cyanin green or other materials by fatty lesions may be used for treatment of acne. Both of these lasers may be used for treatment of hemorrhoids and for podiatric lesions on the feet.

Example 13

A dye laser unit operating at a wavelength of approximately 630 nm or 585 nm, or at other wavelengths which are absorbed by natural porpherins present in P acne bacterias, such as produced by Cynachore or SLS, as well as a laser unit operating at 1.45 microns as produced by Candella, may treat acne lesions. The addition of a diffusing or diverging unit to the laser unit may considerably enhance eye safety and simplify the use of the laser unit for such treatments by nurses and non-medical staff.

Example 14

CO₂, diode and Nd:YAG laser units operating at an average power of

approximately 1-10 W are currently used by physicians to treat pain. The addition of a diffusing unit may enable the use of a highly safe device for that procedure in pain clinics by non- medical personnel. Each laser unit may generate a number of repetitively occurring sets of pulses, during a period of approximately 3 seconds. The delivery system of the laser beam may be an articulated arm or an optical fiber.

Example 15

A diode laser unit manufactured by Candella (USA) generating a laser beam with an energy density of 10 J/cm^2 , a wavelength of 1445 nm, a pulse duration of 100 msec and a spot size of 3 mm is suitable for non-ablative photorejuvenation.

A diverging unit with a single converging lens focuses the beam to a focal zone 1.5 mm proximate to the distal end of the diverging unit and produces a half angle divergence of 45 degrees. The diverging unit is provided with a shield located 10 mm distal to the focal point, whereat the energy density is reduced to an eye safe level of 0.2 J/cm^2 and a spot size is 23 mm.

Example 16

It is advantageous to use an eye-safe laser unit for welding. The employment of a diffusing unit is an excellent way to reduce the risks associated with laser welding.

When welding thin transparent parts, such as those made from plastic, e.g with a diode laser unit, it is often advantageous to employ a large surface scanner or a large diameter beam which will irradiate a large surface area and selectively activate all targets with appropriate chromophores (by heat). Such a scanner is in contrast to a scanner which is specifically targeted to the geometrical locations at which welding materials are

present. The dwelling time of the welding laser beam at the targets depends on the size of the welding element and the depth of material to be melted. The dwelling time is also dependent on the size of a target treated in photothermolysis. As an example, welding a strip having a thickness of 50 micron to a substrate necessitates a dwelling time of approximately 1 msec, while a strip having a thickness of 200 microns requires a dwelling time of 16 msec. The dwelling time is proportional to the square of the thickness. Some welding chromophores are transparent in the visible part of the spectrum, but exhibit strong absorption in the near infrared part of the spectrum.

Example 17

Another industrial application for the present invention is associated with microstructures to be evaporated. Paint stains or ink may be selectively evaporated from surfaces such as clothes, paper and other materials that need cleaning by use of various pulsed lasers. One example of this application is related to the restoration of valued antiques. Another example is the selective vaporization of metallic conductors which are coated on materials such as glass, ceramics or plastics. Vaporization of metallic conductors can be achieved with a pulsed laser, which is generally separated by a short distance from a target and whose beam has a duration ranging from 10 nanoseconds to 10 milliseconds. Pulsed Nd:YAG lasers are the most commonly used ablative industrial lasers, although other lasers are in use as well. Pulsed Nd:YAG industrial lasers may attain an energy level of 20 J concentrated on a spot of 1 mm, equivalent to an energy density of 2000 J/cm². The addition of a diffusing unit to an industrial laser considerably increases the safety of the ablative device.

Pulsed Nd:YAG laser units are also suitable for improving the external appearance of larger structures, such as the cleaning of buildings, stones,

antique sculptures and pottery. The laser units in use today are extremely powerful, having a continuously working power level of up to 1 kW, and are therefore extremely risky. The addition of a diffusing unit considerably improves the safety of these laser units.

A diffusing unit, when attached to an Excimer laser unit, is suitable for photo-lithography, or for other applications which use an Excimer laser unit for a short target distance.

With the addition of a multi-component diffusing or diverging unit, all of these applications become much safer to a user.

While some embodiments of the invention have been described by way of illustration, it will be apparent that the invention can be carried into practice with many modifications, variations and adaptations, and with the use of numerous equivalents or alternative solutions that are within the scope of persons skilled in the art, without departing from the spirit of the invention or exceeding the scope of the claims.

CLAIMS

1. Method of improving bodily safety of bystanders exposed to a monochromatic light source, comprising: providing a monochromatic light source with a distal end, causing said monochromatic light to diverge at said distal end, whereby at a first position of said distal end relative to a target the energy density of an exit beam from said distal end is substantially equal to the energy density of the monochromatic light and at a second position of the distal end relative to a target the energy density of the light emitted from said distal end is significantly less than the energy density of the monochromatic light.

2. Method of claim 1, further comprising

- a) providing a diverging unit transparent to the monochromatic light unit comprising at least one focusing lens, a plurality of reflectors and a distally positioned plate transparent to the monochromatic light;
- b) attaching said diverging unit to the distal end of the monochromatic light source;
- c) focusing the monochromatic light onto at least one of said reflectors; and
- d) allowing light rays to exit said plate at varying angles, depending on the number of times reflected by said reflectors, whereby to cause said monochromatic light to be divergent.

3. Method of claim 1, further comprising the steps of scattering the monochromatic light, said scattered monochromatic light being divergent.

4. Method of claim 3, further comprising:

- a) providing a diffusing unit with a distal end, said diffusing unit comprising at least one diffusively transmitting element, wherein each of

said diffusively transmitting elements is transparent to the monochromatic light;

b) attaching said diffusing unit to the distal end of the monochromatic light source; and

c) allowing the monochromatic light to be scattered by each of said diffusively transmitting elements.

5. Method of claim 3, further comprising:

a) providing a diffusing unit transparent to the monochromatic light comprising an angular beam expander and at least one diffuser;

b) attaching said diffusing unit to the distal end of the monochromatic light source; and

c) allowing the monochromatic light to propagate through said angular beam expander and said at least one diffuser, whereby to scatter said monochromatic light.

6. Method of claim 3, further comprising the following steps:

a) providing a diffusing unit with a plurality of diffusers, wherein at least one diffuser is axially displaceable;

b) axially displacing said at least one axially displaceable diffuser to an active position such that each diffuser is substantially in contact one with the other, whereby the energy density of an exit beam from said diffusing unit is substantially equal to the energy density of the monochromatic light at the first position of the distal end of the monochromatic light source; and

c) axially displacing said at least one axially displaceable diffuser to an inactive position such that each diffuser is separated one from the other by a gap large enough to generate a sufficiently large scattering angle such that the energy density of the light emitted from said diffusing unit at the

second position of the distal end of the monochromatic light source is significantly less than the energy density of the monochromatic light.

7. Method of claim 1, wherein the first position is substantially in contact with a target to which the monochromatic light is directed.

8. Method of any of claims 1 to 6, wherein the radiance of the divergent monochromatic light is less than $14 \text{ J/cm}^2/\text{sr}$.

9. Method of any of claims 1 to 6, wherein the radiance of the divergent monochromatic light is less than $10 \cdot k_1 \cdot k_2 \cdot (t^{1/3}) \text{ J/cm}^2/\text{sr}$, where t is a laser pulse duration in seconds, $k_1=k_2=1$ for a wavelength ranging from 400 to 700 nm, $k_1=1.25$ and $k_2=1$ for a wavelength of approximately 750 nm, $k_1=1.6$ and $k_2=1$ for a wavelength of approximately 810 nm, $k_1=3$ and $k_2=1$ for a wavelength of approximately 940 nm, and $k_1=5$ and $k_2=1$ for a wavelength ranging from 1060 to 1400 nm.

10. Method of claim 1, further comprising measuring the radiance of the divergent monochromatic light and issuing a warning as a result of a mishap if the radiance of the divergent monochromatic light is greater than a predetermined safe value.

11. Method of claim 1, wherein the monochromatic light is selected from the group of collimated laser beam, convergent laser beam, concentrated multiple laser beams and fiber guided laser beam.

12. Method of claim 11, wherein the monochromatic light source is selected from the group of Excimer, Dye, Nd:YAG 1064, 1320 and 440 nm,

frequency doubled Nd:YAG, Ruby, Alexandrite, Diode including diodes operating at a wavelength of 810 to 830 nm, 940nm, and 1450nm, stack of diodes, LICAf, Er:Glass, Er:YAG, Er:YSGG, CO₂, isotopic CO₂ and Holmium lasers.

13. Method of claim 1, wherein the monochromatic light is provided with a wavelength ranging from 308 to 1600 nm or between 1750 nm to 11.5 microns and the energy density level of the monochromatic light source ranges from 0.01 to 2000 J/cm².

14. Method of claim 1, wherein the monochromatic light source is a plurality of monochromatic diodes.

15. Method of claim 1, wherein the bodily safety includes eye safety, skin safety and environmental safety.

16. Method of claim 1, wherein the exit beam at the first position is used in applications selected from the group of cosmetic applications, medical applications and industrial applications.

17. Method of claim 1, wherein the exit beam at the first position is used in applications selected from the group of hair removal, coagulation of blood vessels located on a face or legs, treatment of rosacea, tattoo removal, removal of pigmented lesions in the skin, skin rejuvenation, treatment of psoriasis, treatment of acne, skin resurfacing, skin vaporization, collagen contraction, dental applications, removal of pigments from the gums, teeth whitening, dermatology, gynecology, podiatry, urology, reduction of pain, laser welding of transparent plastic materials, surface treating of materials, laser annealing, evaporation of

paint and ink stains and cleaning of buildings, stones, antique sculptures and pottery.

18. Method of claim 4, wherein a laser beam is controllably repositionable to scan targets of the diffusively transmitting element.

19. Method of claim 18, wherein the sequence of targets to be impinged by the laser beam is programmable.

20. Method of claim 4, further comprising the following steps: providing the diffusing unit with a clear transmitting element such that a gap is formed between a diffusively transmitting element and said clear transmitting element, the diffusively transmitting and clear transmitting elements being transparent to the monochromatic light, placing said clear transmitting element on a target skin location, directing the monochromatic light to said target skin location and cooling skin within said gap.

21. Method of claim 1, wherein a half angle of a divergent exit beam at the first position exceeds 6 degrees.

22. Method of claim 4, wherein a half angle of a divergent exit beam at the first position exceeds 42 degrees.

23. Method of claim 1, wherein the duration of a laser pulse ranges from 1 nanosecond to 1500 msec, and the diameter of a spot size ranges from 1 to 20 mm.

24. Method of claim 23, wherein a series of pulses is generated.

25. Method for converting a laser unit suitable for aesthetic treatment, medical treatment or industrial treatment into an eye safe laser unit, comprising attaching a diverging optical unit to the distal end of a laser unit, allowing monochromatic light to propagate through said unit, generating a non-coherent and extended diffused source of light from said unit at a sufficiently low radiance value such that said source of light is eye safe to bystanders exposed to a monochromatic light source and of a sufficiently high energy density at a treatment location to effect said aesthetic treatment, medical treatment or industrial treatment.

26. Method of claim 25, wherein the unit is a divergent diffusing optical unit.

27. Method of cooling skin which is irradiated with monochromatic light, comprising:

- a) providing a monochromatic light source with a distal end;
- b) providing a unit with two transmitting elements that are transparent to monochromatic light, such that a gap is formed between said two elements;
- c) attaching said unit to the distal end of the monochromatic light source;
- d) placing said unit on a skin location to be treated;
- e) providing means for skin cooling, said skin cooling means being disposed within said gap;
- f) allowing monochromatic light to propagate through said unit to said skin location, the temperature of the skin location to be treated thereby increasing; and
- g) allowing said skin cooling means to cool said skin location.

28. Method of claim 27, further comprising the following steps:

- a) providing the unit with a diffusively transmitting element and with a clear transmitting element distally positioned with respect to said diffusively transmitting element;
- b) allowing the monochromatic light to be scattered by said diffusively transmitting element, whereby the energy density of an exit beam from said clear transmitting element is substantially equal to the energy density of the monochromatic light; and
- c) repositioning the unit from the target to a predetermined position at which the energy density of an exit beam from said diffusively transmitting element is significantly less than the energy density of the monochromatic light.

29. Method of claim 28, wherein the skin cooling means is fluid transparent to the monochromatic light, said fluid flowing through a conduit inserted within the gap.

30. Method of claim 29, wherein the fluid is in fluid communication with an external cooler.

31. Method of claim 27 or 28, wherein the skin cooling means is a thermoelectric cooler, the thermoelectric cooler operative to cool the lateral sides of the transmission element placed on the skin location to be treated.

32. Method of improving eye safety during exposure to a monochromatic light source, comprising: providing a monochromatic light source and generating a visible flash prior to the emission of a pulse of monochromatic light, thereby inducing an eye of a bystander to blink or to change its field of view in order to avoid staring at the monochromatic light.

33. Method of claim 32, wherein the generation of the visible flash is synchronized to the timing of the emission of the monochromatic light pulse.

34. Method of claim 33, wherein the duration of the pulse is shorter than an eye blinking response time.

35. Method of claim 34, wherein the monochromatic light source is suitable for hair removal, photorejuvenation or treatment of vascular lesions.

36. Apparatus for improving bodily safety of bystanders exposed to a monochromatic light source, comprising a means attached to the distal end of a monochromatic light source, said means adapted to cause the monochromatic light to be divergent, whereby at a first position of said distal end relative to a target the energy density of an exit beam from said distal end is substantially equal to the energy density of the monochromatic light and at a second position of said distal end relative to a target the energy density of the light emitted from said distal end is significantly less than the energy density of the monochromatic light.

37. Apparatus of claim 36, wherein the diverging means comprises a diverging unit provided with at least one focusing lens, a plurality of reflectors and a distally positioned plate transparent to the monochromatic light, each of said at least one lens provided with a suitable focal length so as to focus the monochromatic light onto at least one of said reflectors, each of said reflectors positioned so as to allow light rays to exit said plate at varying angles, depending on the number of times reflected by said plurality of reflectors, whereby to cause said monochromatic light to be divergent.

38. Apparatus of claim 36, wherein the diverging means is also a scattering means.

39. Apparatus of claim 38, wherein the scattering means comprises a diffusing unit attachable to the distal end of the monochromatic light source, said diffusing unit including at least one diffusively transmitting element that is transparent to essentially coherent monochromatic light.

40. Apparatus of claim 38, wherein the scattering means comprises a diffusing unit attachable to the distal end of the monochromatic light source, said diffusing unit including an angular beam expander and at least one diffuser.

41. Apparatus of claim 38, wherein the scattering means comprises a diffusing unit attachable to the distal end of the monochromatic light source, said diffusing unit comprising a plurality of diffusers wherein at least one is axially displaceable, such that at an active position the plurality of diffusers are substantially in contact one with the other at the first position of the distal end of the monochromatic light source, and the energy density of an exit beam from said diffusing unit is substantially equal to the energy density of the monochromatic light, and at an inactive position each of said diffusers is separated one from the other by a gap such that the energy density of the light emitted from the diffusing unit is significantly less than the energy density of the monochromatic light at the second position of the distal end of the diffusing unit.

42. Apparatus of claim 36, wherein the first position is substantially in contact with a target to which the monochromatic light is directed.

43. Apparatus of any of claims 36 to 41, wherein the radiance of the divergent monochromatic light is less than $14 \text{ J/cm}^2/\text{sr}$.

44. Apparatus of any of claims 36 to 41, wherein the radiance of the divergent monochromatic light is less than $10 \cdot k_1 \cdot k_2 \cdot (t^{1/3}) \text{ J/cm}^2/\text{sr}$, where t is a laser pulse duration in seconds, $k_1 = k_2 = 1$ for a wavelength ranging from 400 to 700 nm, $k_1 = 1.25$ and $k_2 = 1$ for a wavelength of approximately 750 nm, $k_1 = 1.6$ and $k_2 = 1$ for a wavelength of approximately 810 nm, $k_1 = 3$ and $k_2 = 1$ for a wavelength of approximately 940 nm, and $k_1 = 5$ and $k_2 = 1$ for a wavelength ranging from 1060 to 1400 nm.

45. Apparatus of claim 36, wherein the monochromatic light is selected from the group of collimated laser beam, convergent laser beam, concentrated multiple laser beams and fiber guided laser beam.

46. Apparatus of claim 45, wherein the monochromatic light source is selected from the group of Excimer, Dye, Nd:YAG 1064, 1320 and 1440 nm, frequency doubled Nd:YAG, Ruby, Alexandrite, Diode including diodes operating at a wavelength of 810 to 830 nm, 940nm, and 1450nm, stack of diodes, LICAf, Er:Glass, Er:YAG, Er:YSGG, CO₂, isotopic CO₂ and Holmium laser units.

47. Apparatus of claim 36, wherein the monochromatic light is provided with a wavelength ranging from 308 to 1600 nm or between 1750 nm to 11.5 microns and the energy density level of the monochromatic light source ranges from 0.01 to 2000 J/cm².

48. Apparatus of claim 36, wherein the monochromatic light source is a plurality of monochromatic diodes.

49. Apparatus of claim 36, wherein the bodily safety includes eye safety, skin safety and environmental safety.

50. Apparatus of claim 36, wherein the exit beam at the first position is used in applications selected from the group of cosmetic applications, medical applications and industrial applications.

51. Apparatus of claim 36, wherein the exit beam at the first position is used in applications selected from the group of hair removal, coagulation of blood vessels located on a face or legs, treatment of rosacea, tattoo removal, removal of pigmented lesions in the skin, skin rejuvenation, treatment of psoriasis, treatment of acne, skin resurfacing, skin vaporization, collagen contraction, dental applications, removal of pigments from the gums, teeth whitening, dermatology, gynecology, podiatry, urology, reduction of pain, laser welding of transparent plastic materials, surface treating of materials, laser annealing, evaporation of paint and ink stains and cleaning of buildings, stones, antique sculptures and pottery.

52. Apparatus of claim 45, wherein the duration of a laser pulse ranges from 1 nanosecond to 1500 msec.

53. Apparatus of claim 46, wherein the laser unit is provided with a power level ranging from 1 to 2000 W, when under continuously working operation.

54. Apparatus of claim 39, wherein the material of each diffusively transmitting element is selected from the group of silica, glass, sapphire,

diamond, non-absorbing polymer, light diffusing polymer, polycarbonate, acrylic, densely packed fibers, NaCl, CaF₂, glass, ZnSe and BaF₂.

55. Apparatus of claim 39, wherein the diffusing unit is further provided with a clear transmitting element distal to a diffusively transmitting element, the diffusively transmitting element and clear transmitting elements being mutually parallel and perpendicular to the longitudinal axis of the diffusing unit.

56. Apparatus of claim 55, wherein the clear transmitting element is made of a material selected from the group of glass, sapphire, transparent polymer including polycarbonate and acrylic, BaF₂, NaCl and ZnF₂.

57. Apparatus of claim 55, wherein a gap between the diffusively transmitting and clear transmitting elements is less than 2 mm.

58. Apparatus of claim 39, wherein each diffusively transmitting element is provided with a plurality of irregularities which are randomly distributed thereabout.

59. Apparatus of claim 39, wherein the diffusively transmitting element is formed by a diffraction pattern or by a randomly distributed array of thin fibers.

60. Apparatus of claim 40, wherein the diffusing unit further comprises at least one light guide, each of said light guides being provided with internally reflecting walls and an exit surface.

61. Apparatus of claim 60, wherein a light guide is tapered.

62. Apparatus of claim 60, wherein a light guide is made of a material selected from the group of solid glass, sapphire, plastic and liquid dielectric material.

63. Apparatus of claim 60, further comprising an optical element which increases the divergence angle of monochromatic light and a diffuser which receives light from said optical element and emits said received light to the light guide, the exit surface of said light guide functioning as a wide angle extended diffuser source.

64. Apparatus of claim 39, further comprising a plurality of reflectors, the angular disposition and distance of each reflector relative to the diffusing unit being repositionable, whereby to accurately direct the monochromatic light to a selected target on the diffusively transmitting element.

65. Apparatus of claim 64, further comprising a processor, said processor suitable for the programming of the sequence of targets to be impinged by the monochromatic light.

66. Apparatus of claim 39, further comprising a scanner for rapid repositioning of the monochromatic light to a target on the diffusively transmitting element.

67. Apparatus of claim 36, wherein the distance between a distal end of the diverging means and the target at the first position of the distal end of the monochromatic light source is the smaller of 2 mm and the diameter of the monochromatic light.

68. Apparatus of any of claims 37 to 41, wherein a unit is attached to the distal end of the monochromatic light source by an attachment means.

69. Apparatus of claim 68, wherein the unit is fixedly attached to the distal end of the monochromatic light source.

70. Apparatus of claim 68, wherein the unit is integrally formed together with the distal end of the monochromatic light source during manufacturing, the unit being disposed internally to the outer wall of the monochromatic light source.

71. Apparatus of claim 68, wherein the attachment means is releasable.

72. Apparatus of claim 71, wherein the attachment means is permanently attached to the monochromatic light source and displaceable, whereby in one position of a displaceable unit the monochromatic light source is coherent, not propagating through said displaceable unit, and in a second position at which said displaceable unit is attached to the distal end of the monochromatic light source, the monochromatic light is noncoherent, propagating through the displaceable unit.

73. Apparatus of claim 36, wherein a divergent angle of the divergent monochromatic light is greater than a half angle of 6 degrees.

74. Apparatus of claim 39, wherein a half angle of a scattered exit beam exceeds 42 degrees.

75. Apparatus of claims 37 to 41, further comprising a means to evacuate vapors or particles from a target to thereby prevent a change in optical properties of the unit.

76. Apparatus of claim 75, wherein the evacuation means is U-shaped in vertical cross-transmission element, to allow for contact with a target at its lateral ends and for evacuation of vapors or particles through a gap formed by its central open region.

77. Apparatus of claim 75, the evacuation means further comprising a relay optics device, whereby to concentrate the exit beam from the unit onto the target.

78. Apparatus of claim 55, further comprising a means for skin cooling, said skin cooling means being disposed in a gap formed between the frosted and clear transmitting elements.

79. Apparatus of claim 36, further comprising a means for measuring the radiance of the divergent monochromatic light, control circuitry in communication with said measuring means and the monochromatic light source, and a warning means in communication with said control circuitry which is activated, as a result of a mishap, if the radiance of the divergent monochromatic light is greater than a predetermined safe value.

80. Apparatus of claim 36, further comprising a means for generating a visible flash and control circuitry in communication with said means for generating a visible flash and with the monochromatic light source, said control circuitry synchronized such that a flash is generated prior to the emission of each pulse of monochromatic light.

81. Apparatus of claim 36, wherein the monochromatic light source is one or more arrays of a diode light source.

82. Apparatus for cooling skin which is irradiated with monochromatic light, comprising:

- a) a monochromatic light source with a distal end;
- b) a unit attachable to the distal end of the monochromatic light source, said unit being provided with two elements that are transparent to monochromatic light, such that a gap is formed between said two elements; and
- c) a means for skin cooling insertable within said gap, said skin cooling means adapted to reduce the rate of increase of temperature at a target skin location.

83. Apparatus of claim 82, wherein one element is a diffusively transmitting element and the other element is a clear transmitting element distally positioned with respect to said diffusively transmitting element, whereby the energy density of an exit beam from the diffusing unit is substantially equal to the energy density of the monochromatic light upon placement of the diffusing unit at a position adjacent to a target skin location and is significantly less than the energy density of the monochromatic light at a distance from said target.

84. Apparatus of claim 82, wherein the skin cooling means is a fluid transparent to said monochromatic light, said fluid flowable through a conduit inserted within the gap.

85. Apparatus of claim 84, wherein the fluid is in fluid communication with an external cooler.

86. Apparatus of claim 84, wherein the fluid is a liquid or a gas.

87. Apparatus of claim 82 or 83, wherein the skin cooling means is a thermoelectric cooler, the thermoelectric cooler operative to cool the lateral sides of the element placed adjacent to the skin location to be treated.

88. Apparatus of any of claims 82 to 87, further comprising a scanner, said scanner being adapted to rapidly reposition the monochromatic light to a target on the diffusively transmitting element, the skin cooling means capable of continuously cooling the skin at a corresponding target skin location.

89. Apparatus for improving eye safety during exposure to a monochromatic light source, comprising: a monochromatic light source, a means for generating a visible flash prior to emission of a monochromatic light, and control circuitry in communication with said means for generating a visible flash.

90. Apparatus of claim 89, wherein the control circuitry is synchronized such that the flash is generated prior to the emission of each pulse of monochromatic light, thereby inducing an eye of a bystander to blink or to change its field of view in order to avoid staring at the monochromatic light.

91. Apparatus of claim 90, wherein the duration of the pulse is shorter than an eye blinking response time.

92. Apparatus of claim 89, wherein the monochromatic light source is suitable for hair removal, photorejuvenation or treatment of vascular lesions.

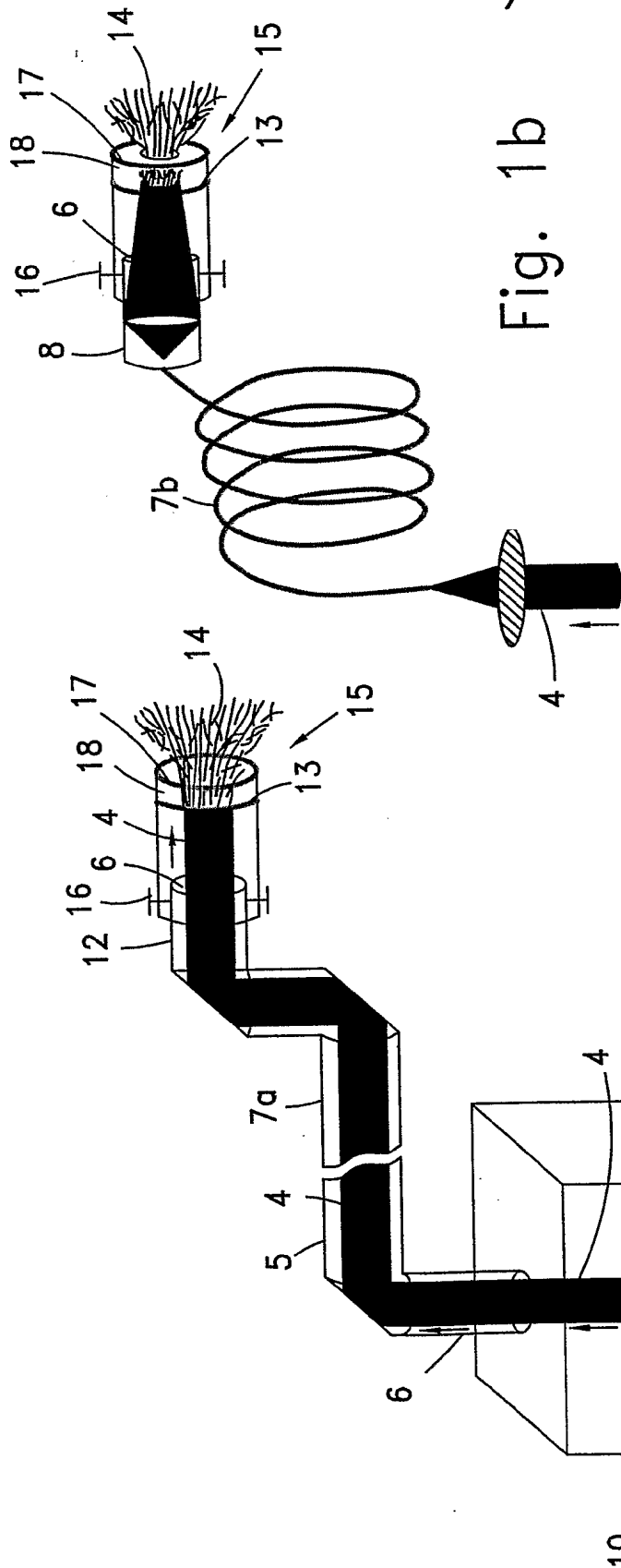


Fig. 1b

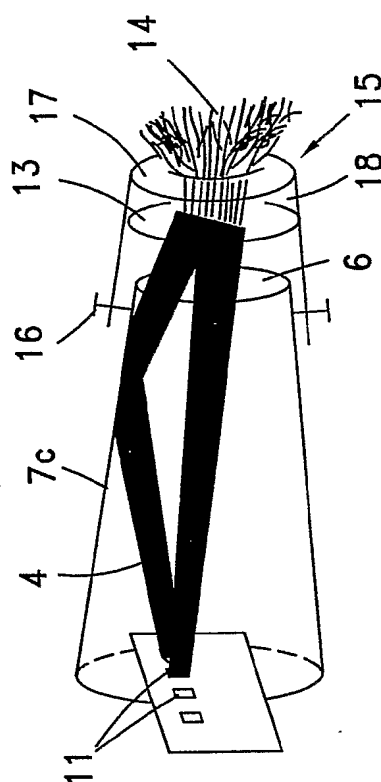


Fig. 1c

Fig. 1a

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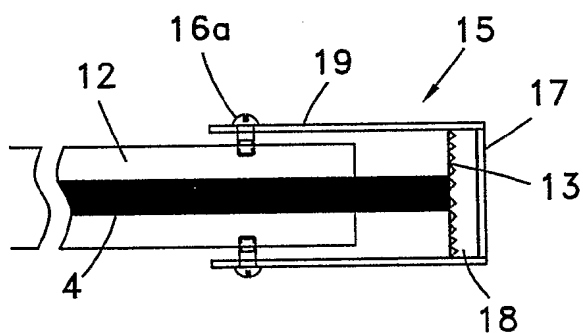


Fig. 2a

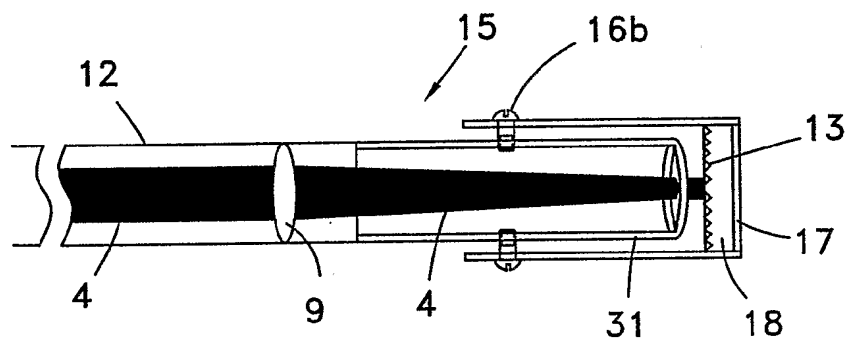


Fig. 2b

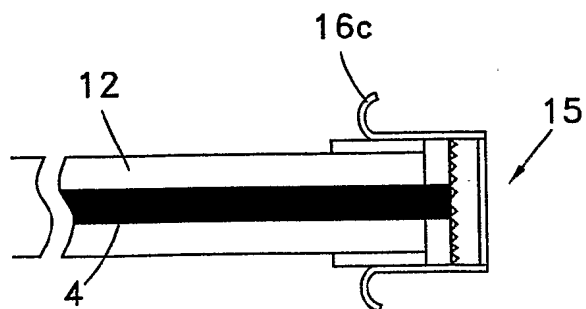


Fig. 2c

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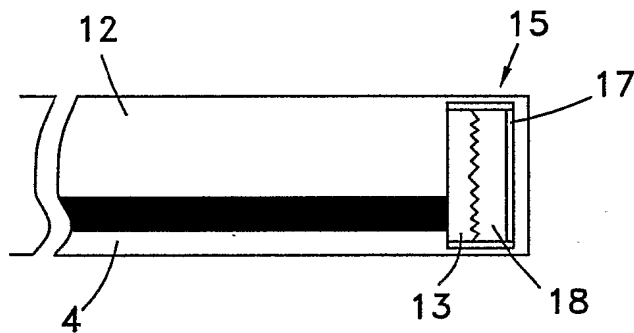


Fig. 2d

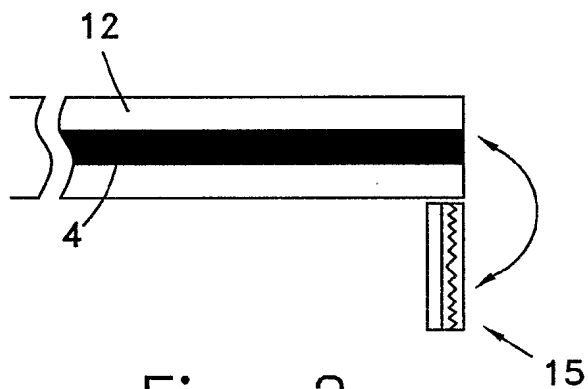


Fig. 2e

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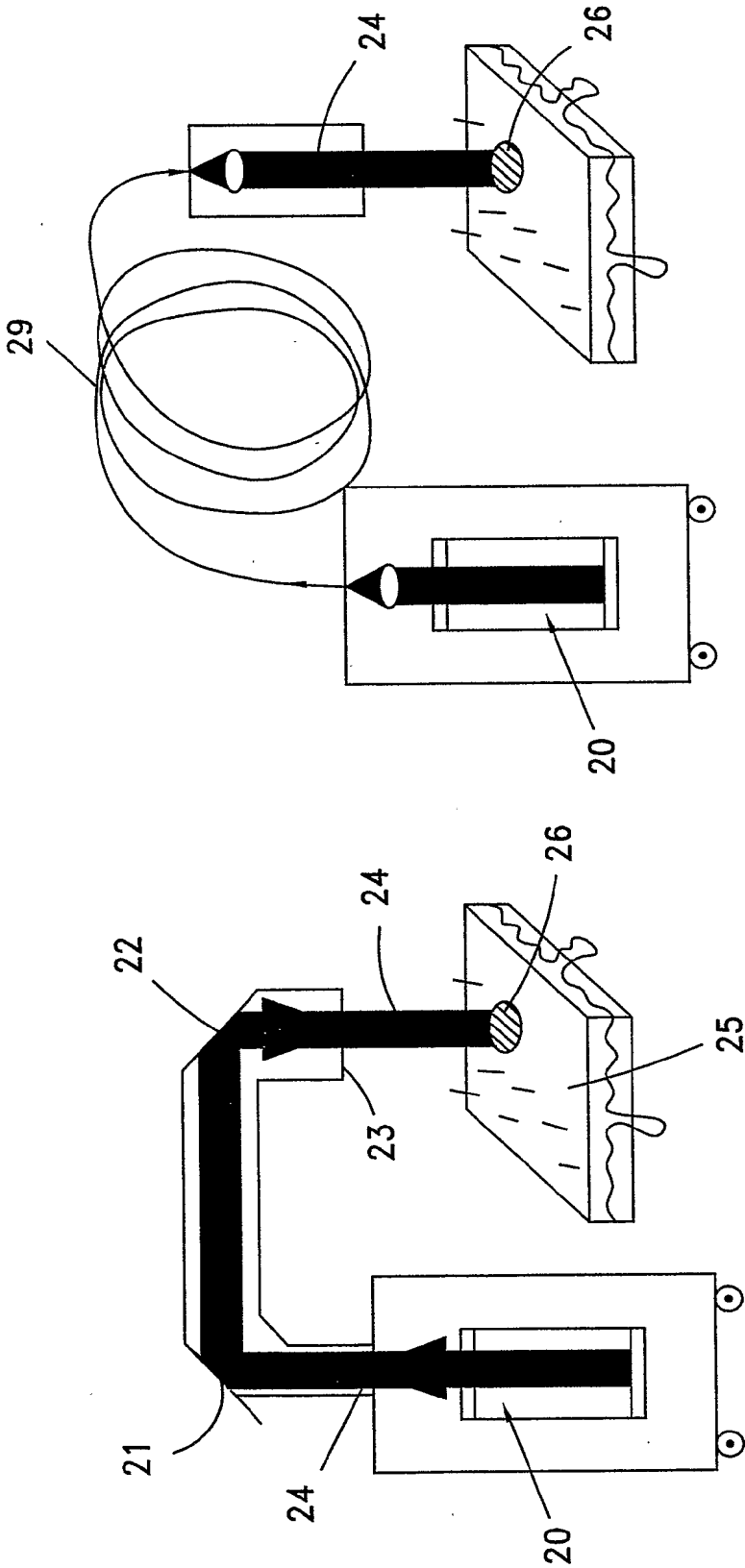


Fig. 3b

PRIOR ART

Fig. 3a

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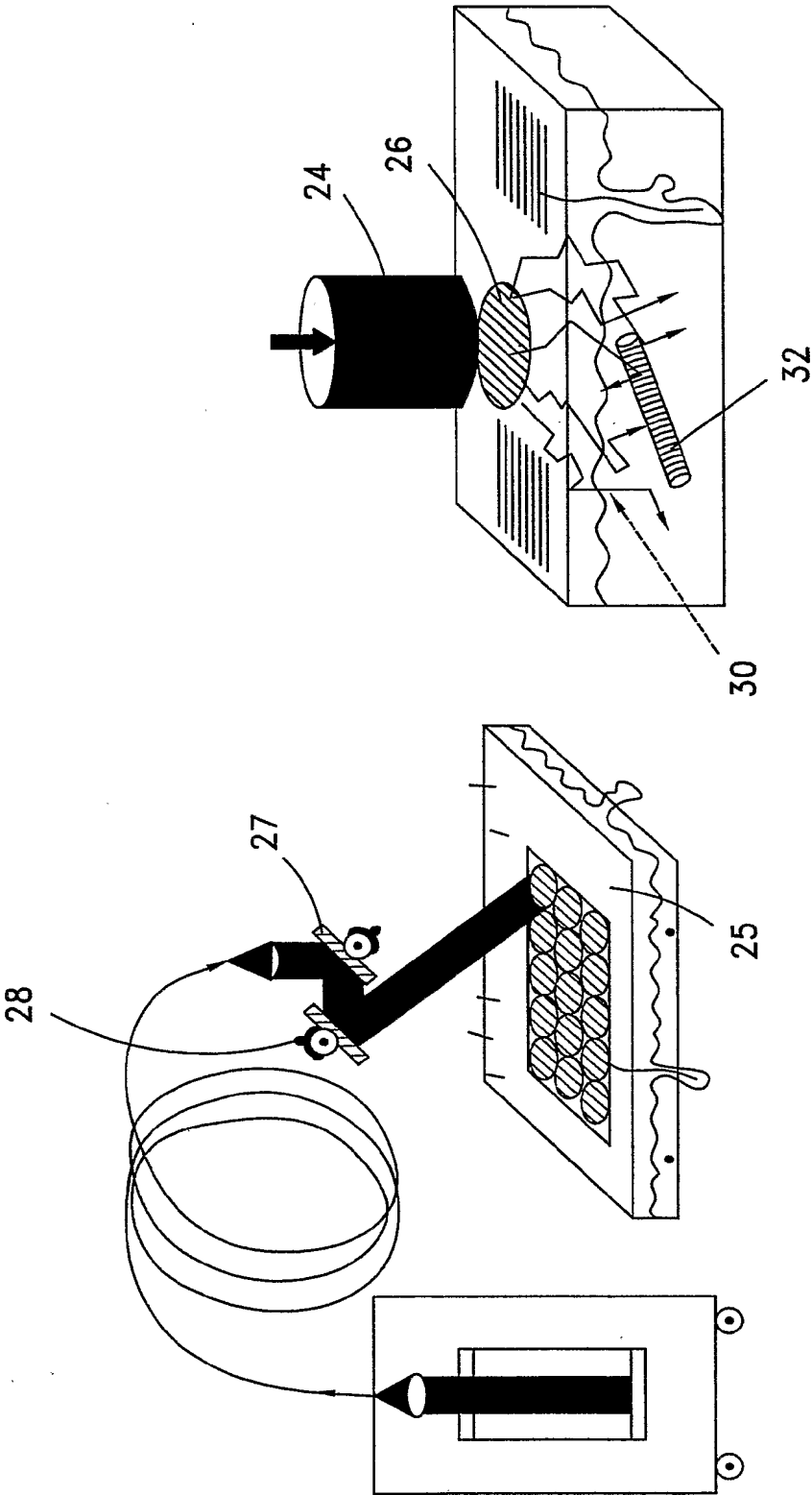


Fig. 3d

Fig. 3c

PRIOR ART

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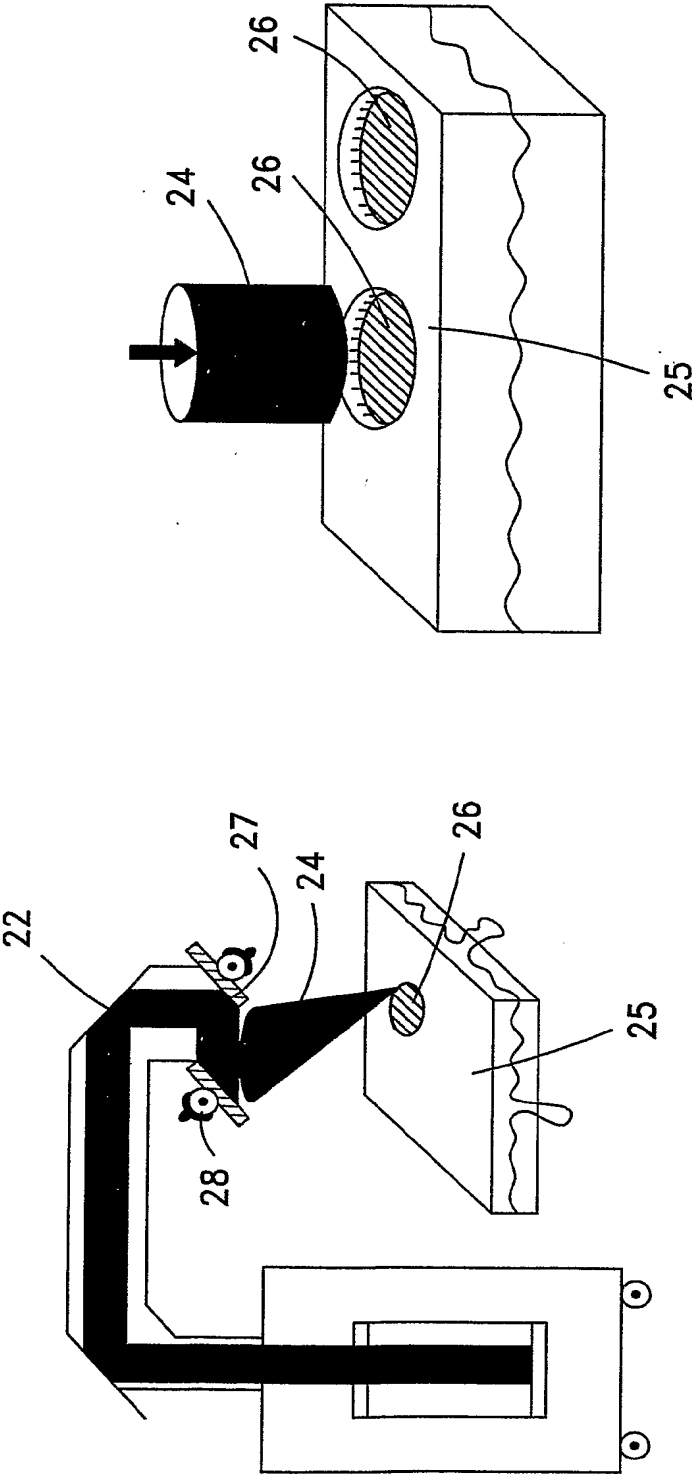


Fig. 3f

Fig. 3e
PRIOR ART

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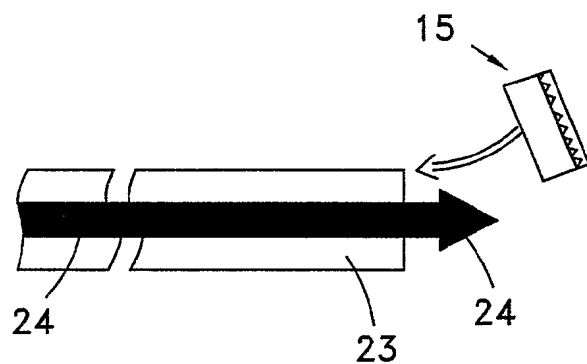


Fig. 4a

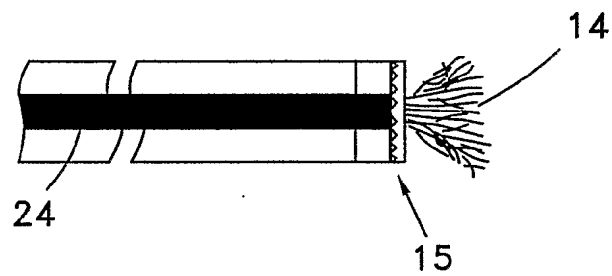


Fig. 4b

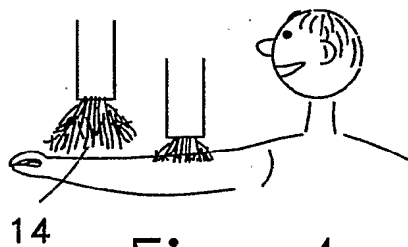


Fig. 4c

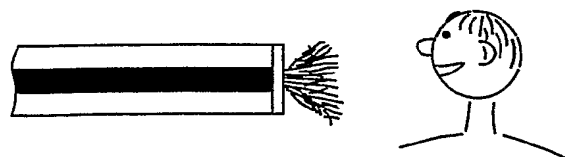


Fig. 4d

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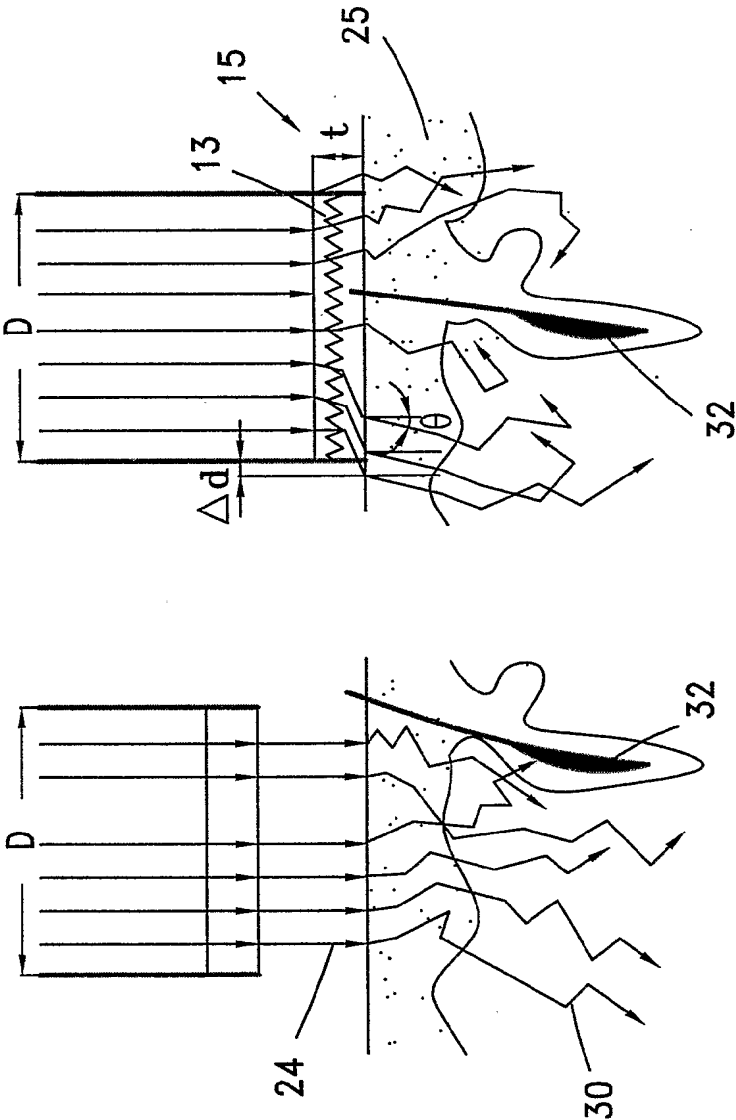


Fig. 5b

Fig. 5a
(PRIOR ART)

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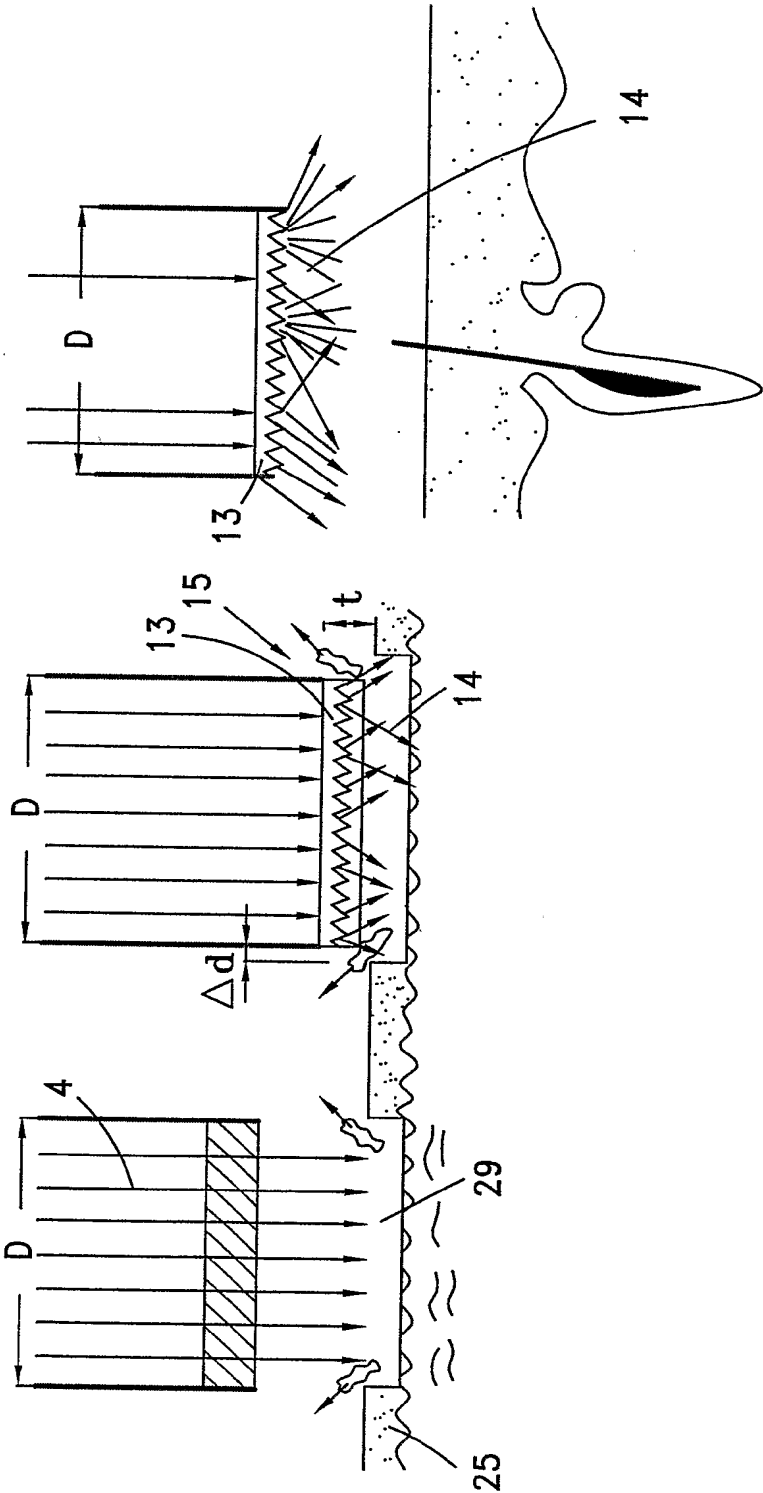


Fig. 5e

Fig. 5d

Fig. 5c
(PRIOR ART)

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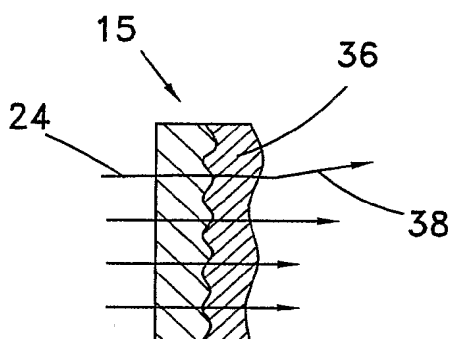


Fig. 6a

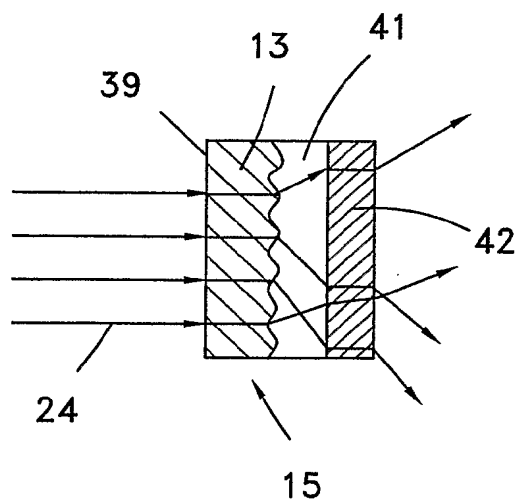


Fig. 6b

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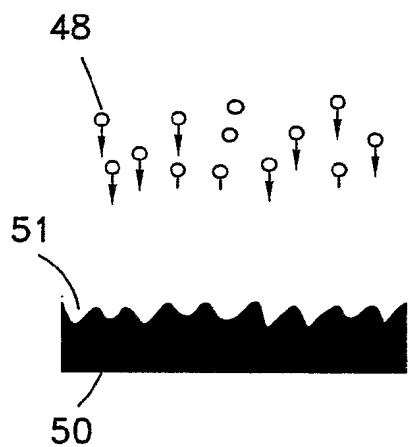


Fig. 7a

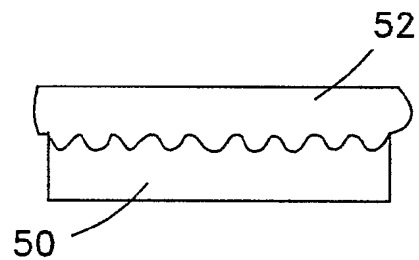


Fig. 7b

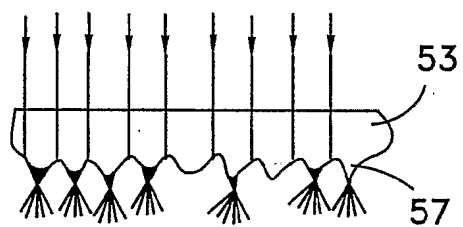


Fig. 7d

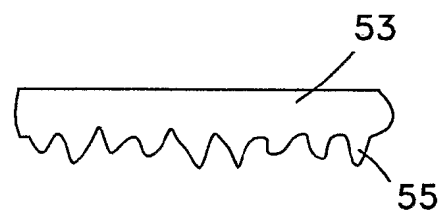


Fig. 7c

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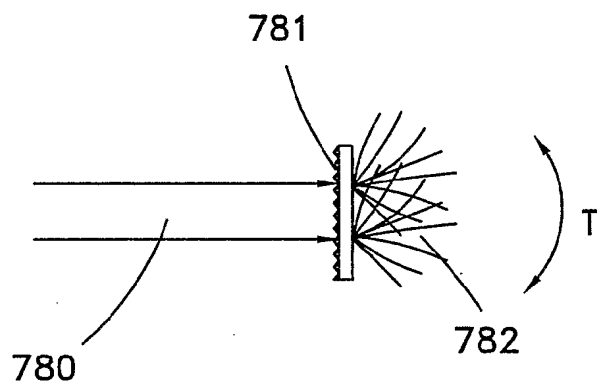


Fig. 8a

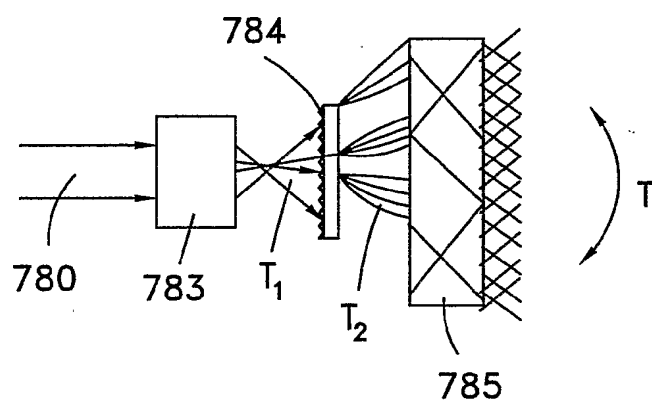


Fig. 8b

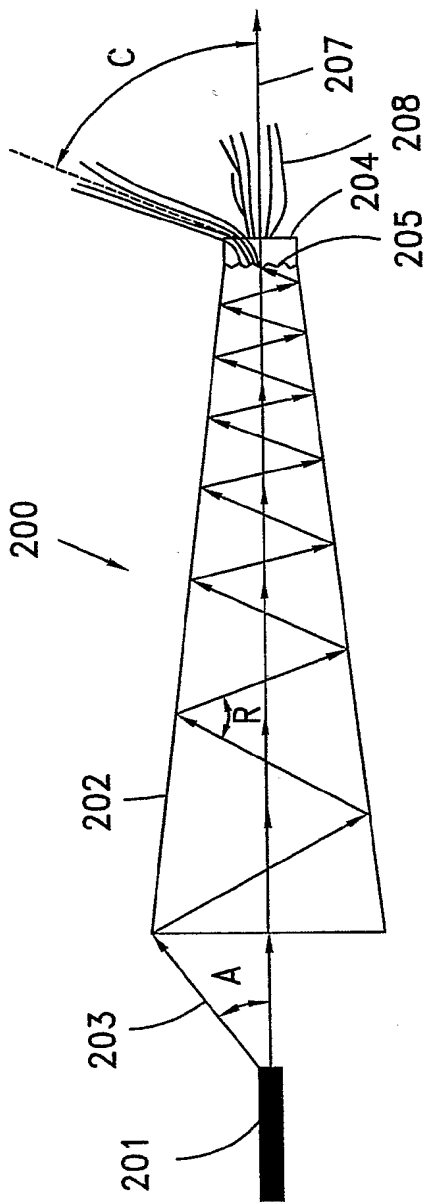


Fig. 9a

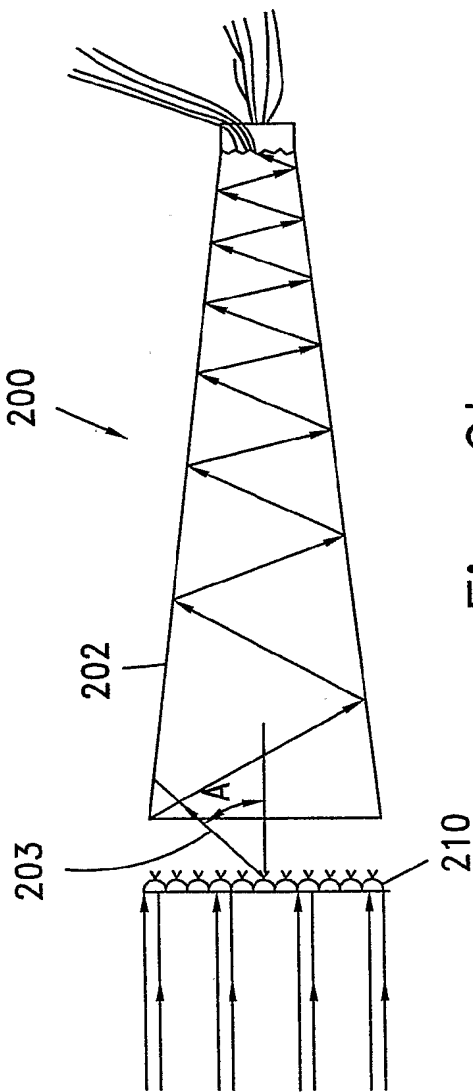


Fig. 9b

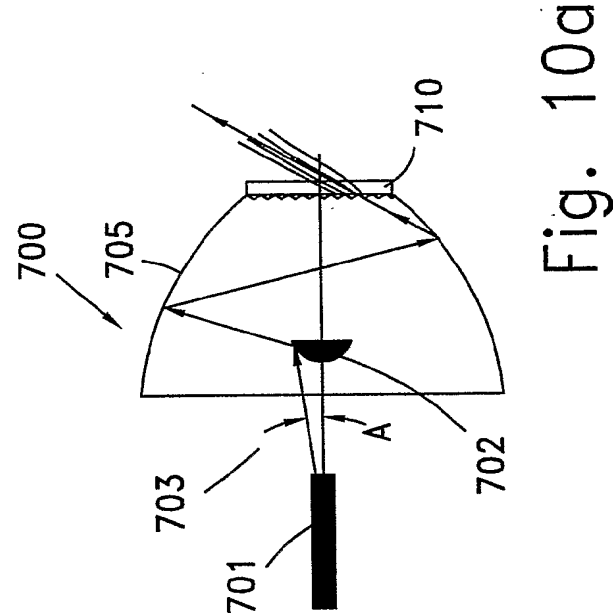


Fig. 10a

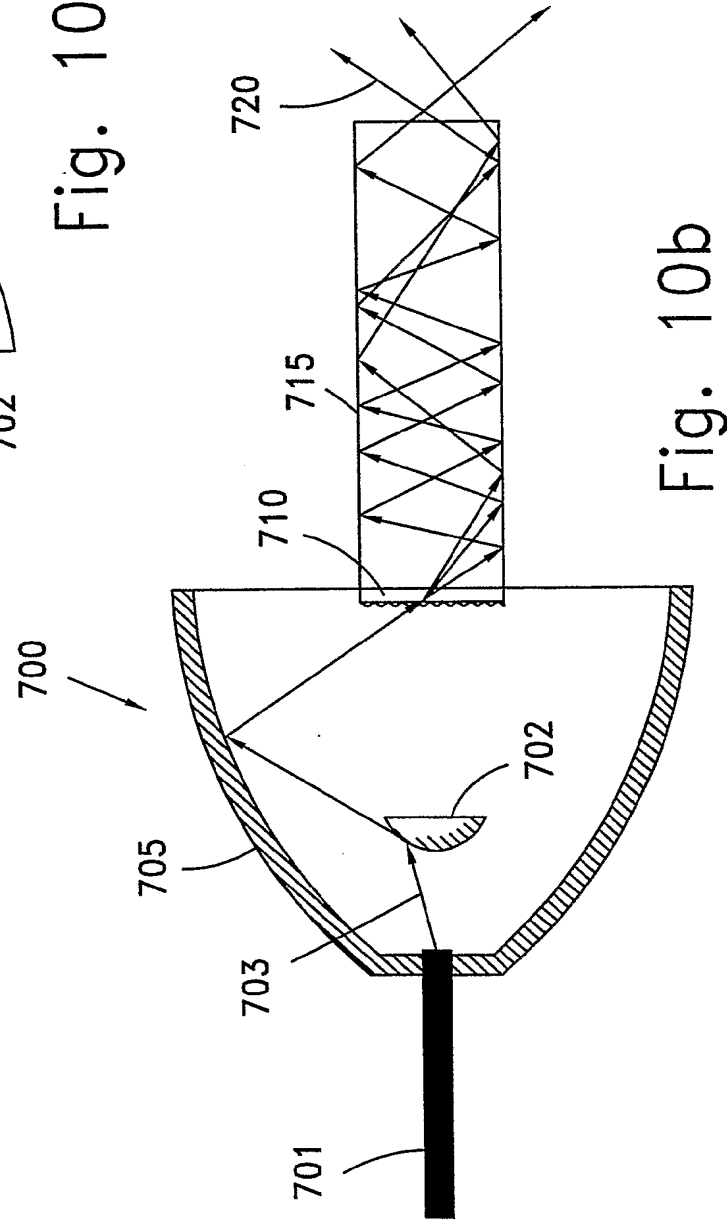


Fig. 10b

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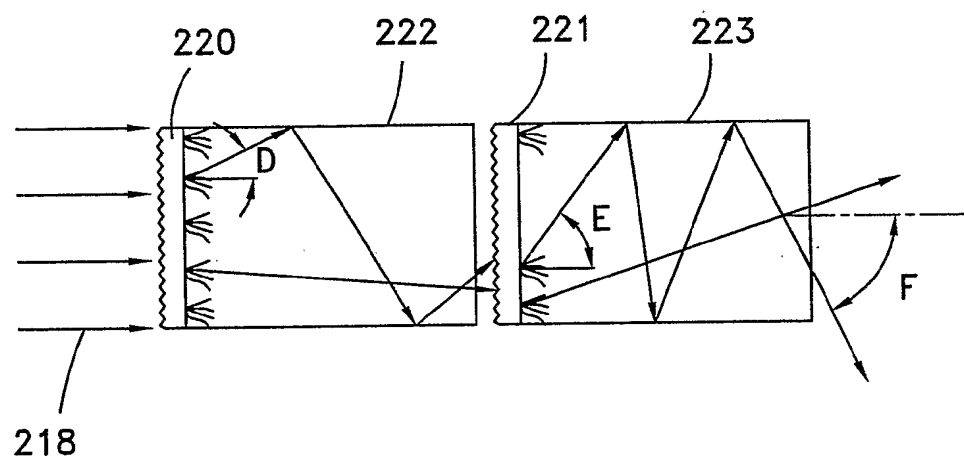


Fig. 11

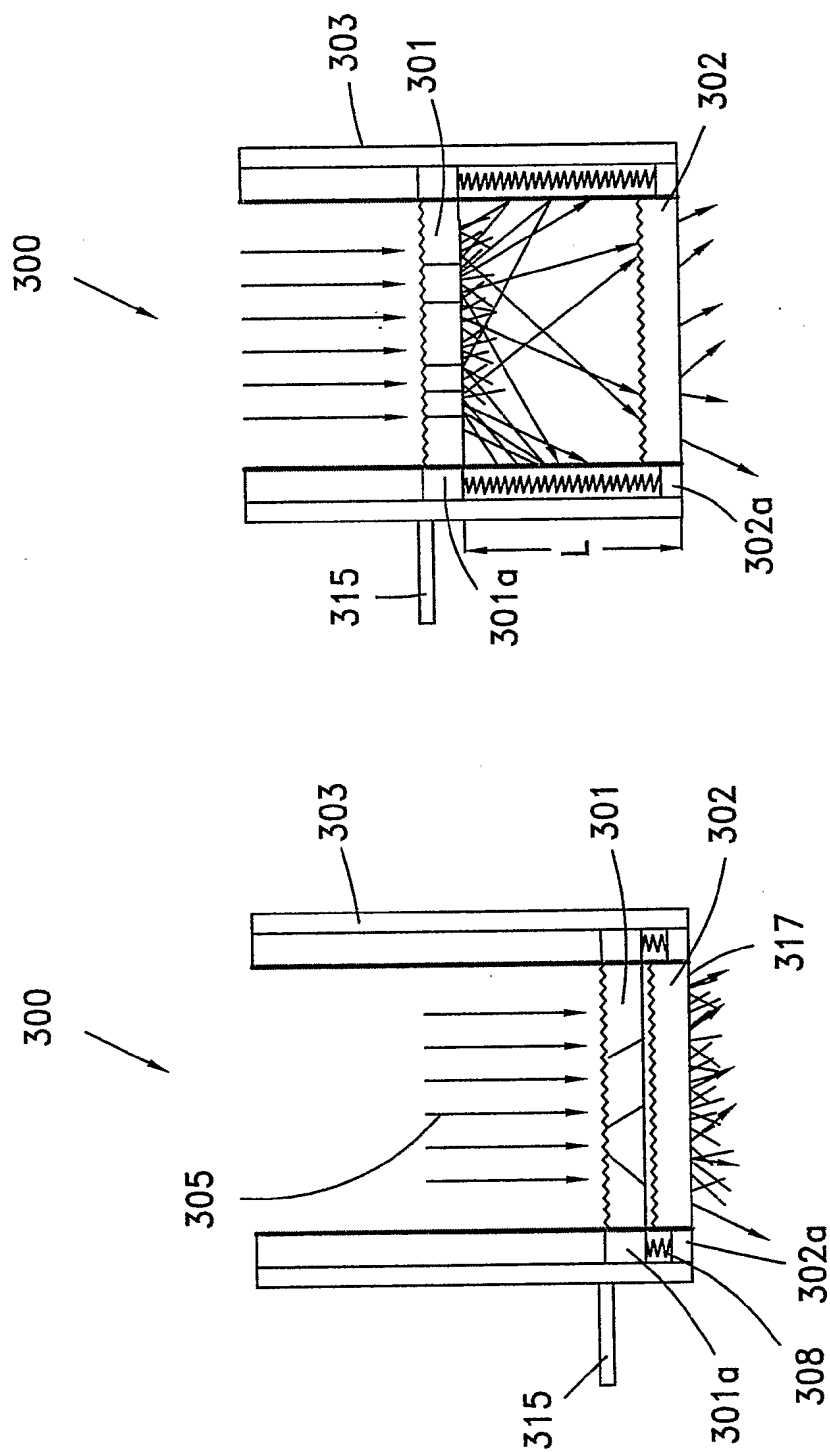


Fig. 12a

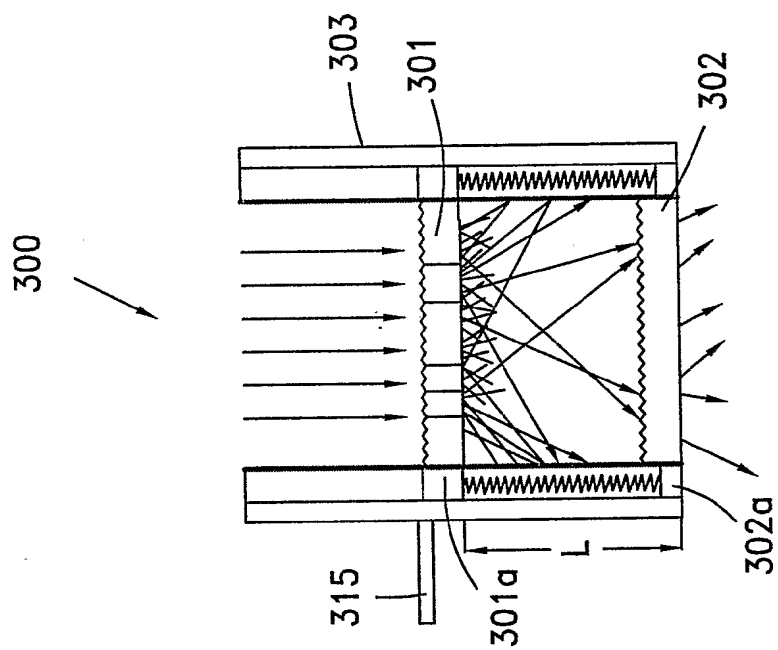


Fig. 12b

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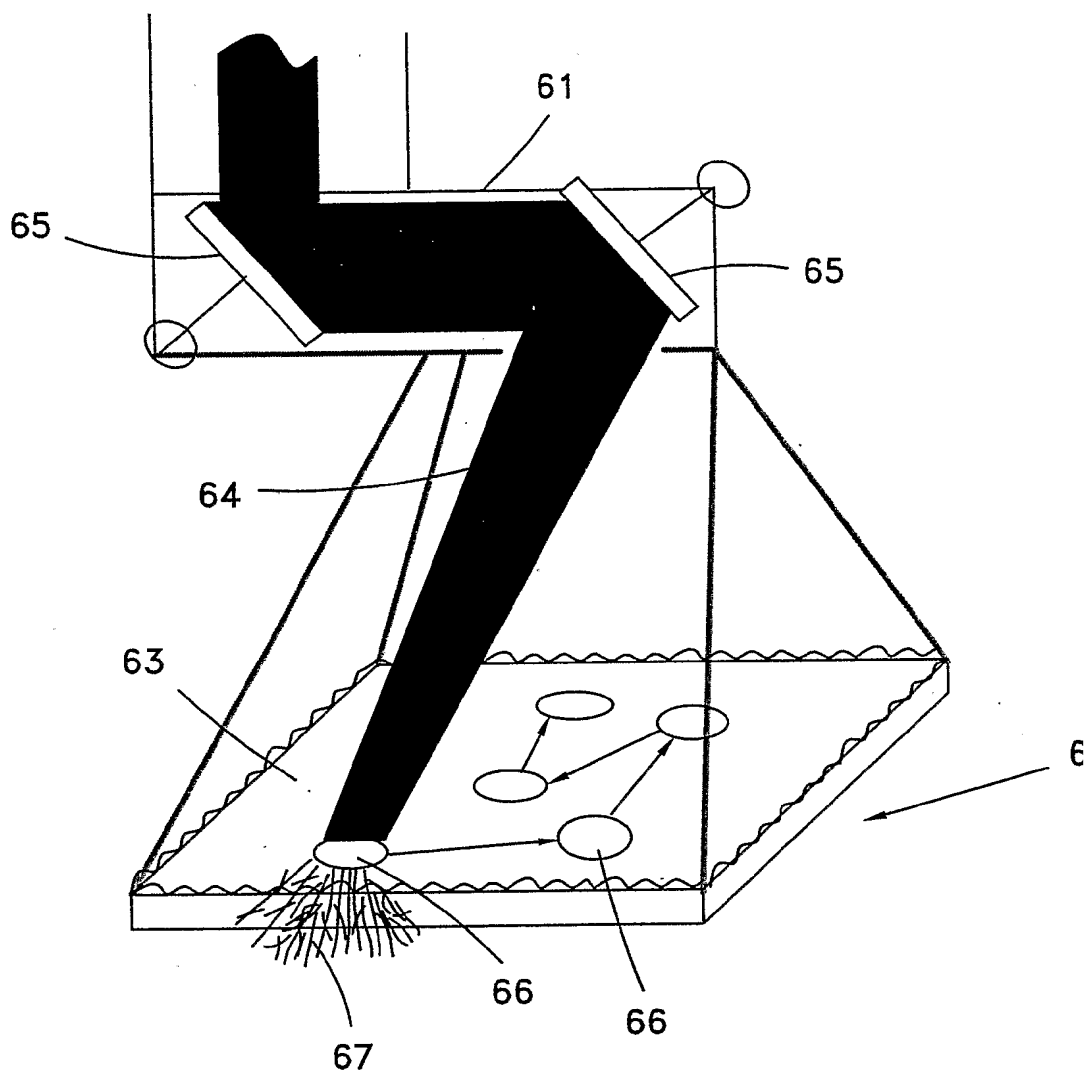


Fig. 13

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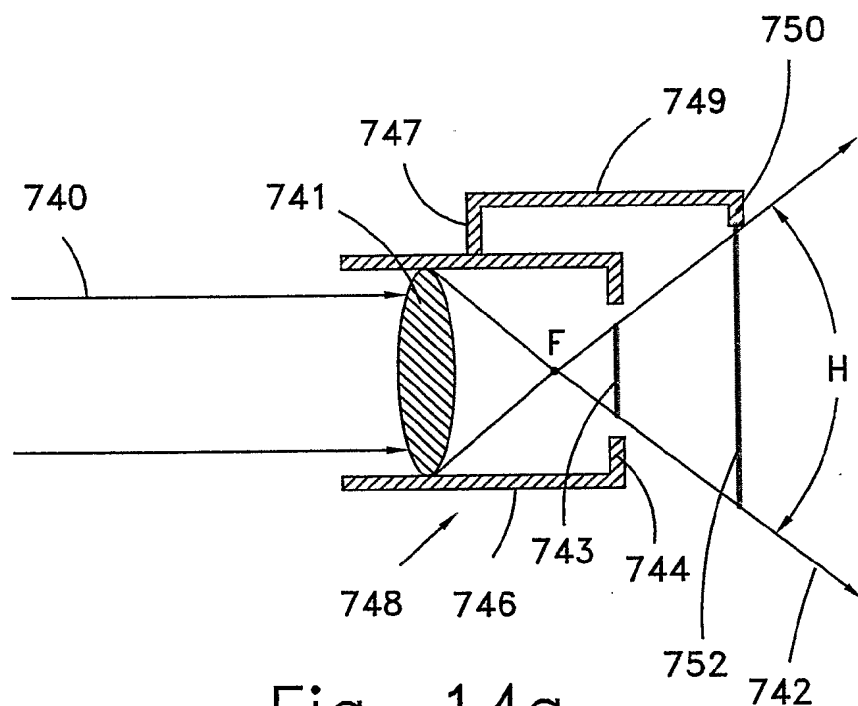


Fig. 14a

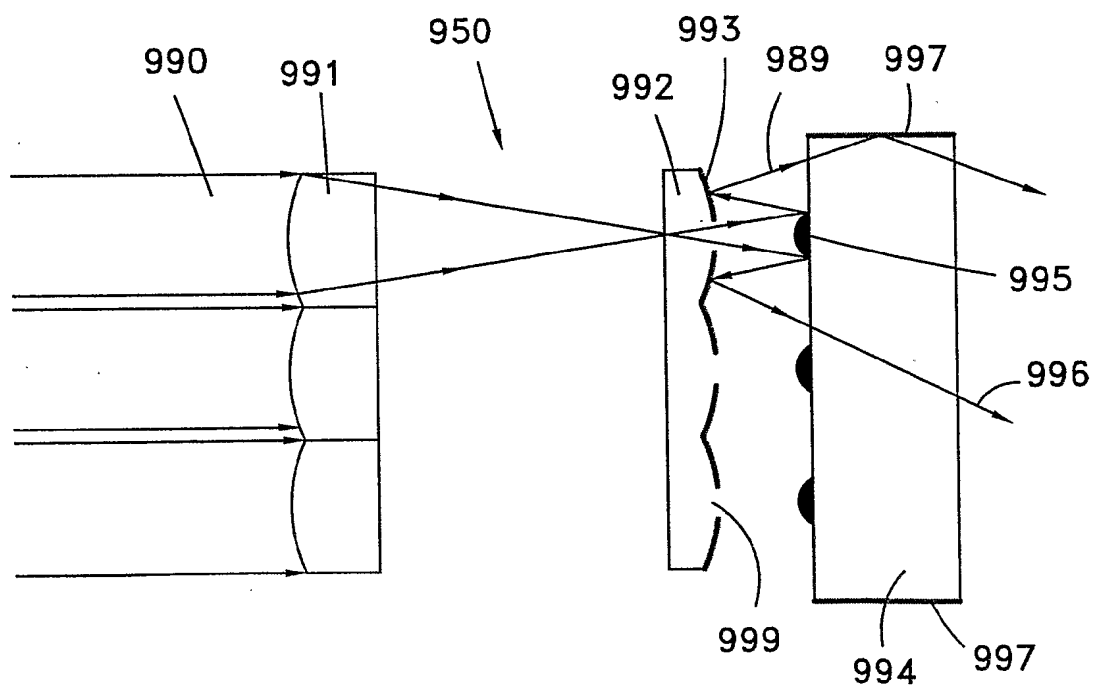


Fig. 14b

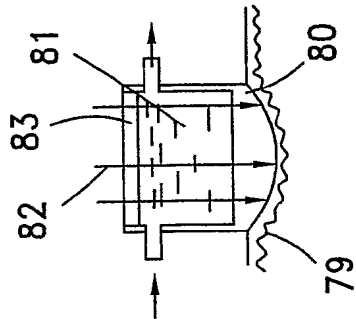


Fig. 15a
(PRIOR ART)

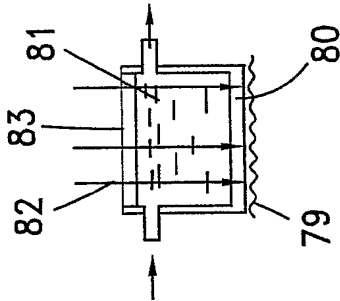


Fig. 15b
(PRIOR ART)

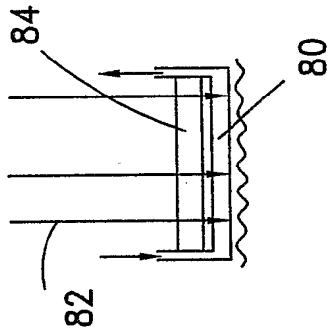


Fig. 15c
(PRIOR ART)

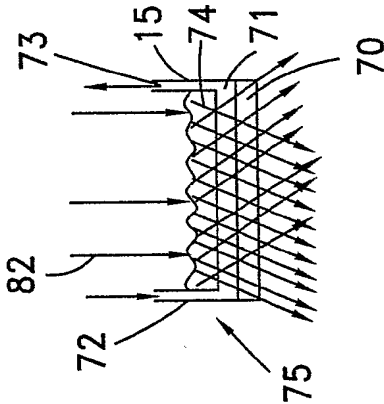


Fig. 15e

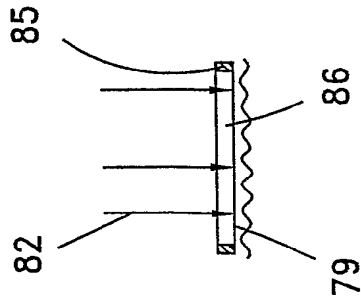


Fig. 15d
(PRIOR ART)

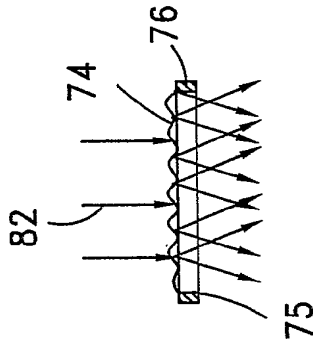


Fig. 15f

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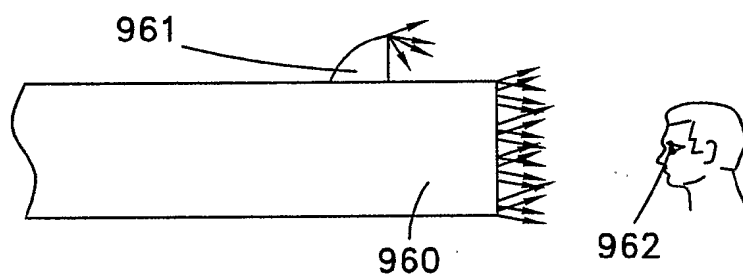


Fig. 17a

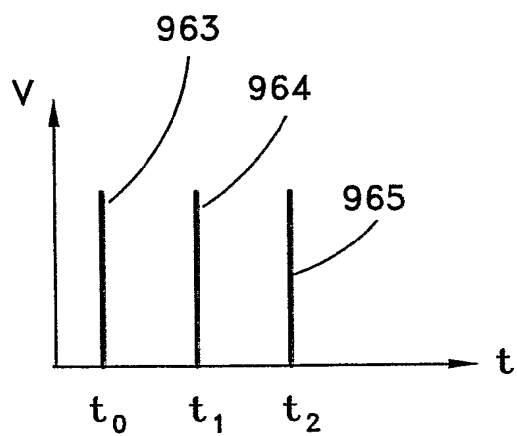


Fig. 17b

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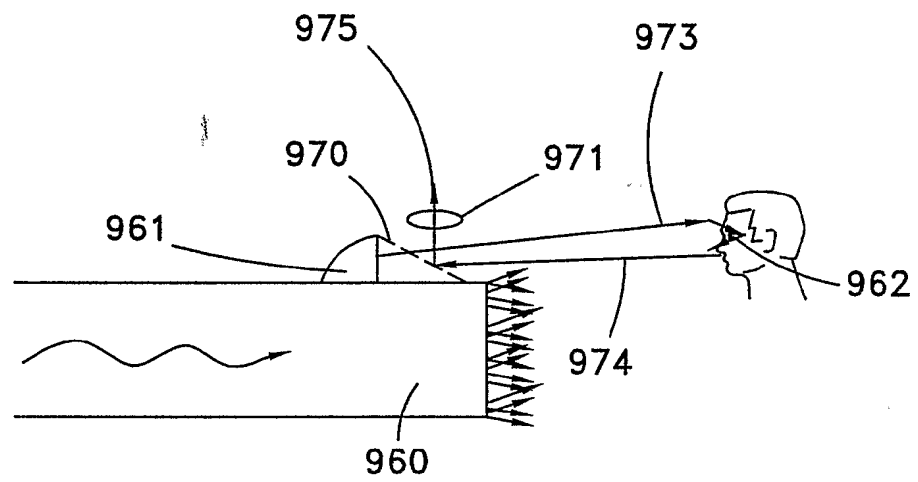


Fig. 17c

INTERNATIONAL SEARCH REPORT

 Intern al Application No
 PCT/IL 02/00635

 A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61B19/00 A61B18/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 60711 A (SHIMONAKA ATSUSHI ;EMOTO KAZUHIRO (JP); SHARP KK (JP); KAWANISHI H) 12 October 2000 (2000-10-12) abstract; figure 1 --- -/--	1,3-5,8, 9,11-13, 15,16, 21-23, 25,26, 36,38, 42-47, 49,50, 52-54, 67,73

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

2 December 2002

Date of mailing of the international search report

28.02.2003

Name and mailing address of the ISA

 European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Mayer, E

INTERNATIONAL SEARCH REPORT

Inter: al Application No
PCT/IL 02/00635

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 761 257 A (MATSUSHITA ELECTRIC IND CO LTD) 12 March 1997 (1997-03-12)	1,3-5, 11-17, 21-26, 36, 38-40, 42-54, 58-62, 67-74,81
A	column 5, line 56 -column 6, line 45; figure 1 ---	2,6-10, 18-20
X	EP 1 116 476 A (INDIGO MED INC) 18 July 2001 (2001-07-18)	36, 38-40, 42-54, 58-62, 67-74,81
A	column 8, line 18 - line 51; figures 5,6 ---	1
X	US 5 401 270 A (SCHOENBORN KARL-HEINZ ET AL) 28 March 1995 (1995-03-28)	36
A	column 5, line 34 - line 45; figure 3A ---	1
X	US 4 592 353 A (DAIKUZONO NORIO) 3 June 1986 (1986-06-03)	36, 42-53, 67,73,81
A	column 6, line 58 - line 65; figure 2 ---	1
X	US 5 431 647 A (PURCELL JR EARL E ET AL) 11 July 1995 (1995-07-11) abstract; figure 1 ---	36
A	EP 0 933 096 A (IBM) 4 August 1999 (1999-08-04) column 19, line 1 - line 7; figure 9 -----	79

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL 02/00635

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 27-31
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-26, 36-81

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-26,36-81

safety method and apparatus with monochromatic light and diverging means

2. Claims: 32-35,89-92

safety method and apparatus with a visible flash prior to monochromatic pulse

3. Claims: 82-88

apparatus for skin cooling with transparent members and cooling medium therebetween

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IL 02/00635

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0060711	A	12-10-2000	EP 1168535 A1 WO 0060711 A1	02-01-2002 12-10-2000
EP 0761257	A	12-03-1997	JP 9122259 A EP 0761257 A2 US 5871521 A	13-05-1997 12-03-1997 16-02-1999
EP 1116476	A	18-07-2001	EP 1116476 A2 EP 0792663 A2 EP 0792664 A2 AU 1870592 A DE 69226634 D1 DE 69226634 T2 DE 69232225 D1 DE 69232225 T2 DE 69232712 D1 DE 69232712 T2 EP 0582686 A1 JP 6509949 T WO 9217243 A2	18-07-2001 03-09-1997 03-09-1997 02-11-1992 17-09-1998 04-03-1999 03-01-2002 23-05-2002 05-09-2002 06-02-2003 16-02-1994 10-11-1994 15-10-1992
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US 4592353	A	03-06-1986	AU 3155584 A EP 0187744 A1 JP 5086225 B JP 61502168 T WO 8505263 A1	13-12-1985 23-07-1986 10-12-1993 02-10-1986 05-12-1985
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EP 0933096	A	04-08-1999	US 6165170 A CN 1233454 A EP 0933096 A2 JP 3229280 B2 JP 11267131 A TW 403667 B US 6447503 B1	26-12-2000 03-11-1999 04-08-1999 19-11-2001 05-10-1999 01-09-2000 10-09-2002

**METHOD AND APPARATUS FOR PHOTOTHERMAL
TREATMENT OF TISSUE AT DEPTH**

CROSS-REFERENCE TO RELATED APPLICATION

This invention claims the benefit of co-pending U.S. Provisional Patent Application Serial No. 60/389,871, filed June 19, 2002, entitled "Method and Apparatus for Subdermal Heating," by G. Altshuler, et al., incorporated herein by reference in its entirety.

BACKGROUND

Field of the Invention

This invention relates to methods and apparatus for the photothermal treatment of tissue and, more particularly, to methods and apparatus for photothermal treatment of at least a selected region of tissue located starting at a depth at about the boundary zone of dermal and subdermal tissue and extending therebelow.

Description of the Related Art

The benefits of being able to raise and/or lower the temperature in a selected region of tissue for various therapeutic and cosmetic purposes has been known for some time. For instance, heated pads or plates or various forms of electromagnetic radiation, including microwave radiation, electricity, infrared radiation and ultrasound have previously been used for heating subdermal muscles, ligaments, bones and the like to, for example, increase blood flow, to otherwise promote the healing of various injuries and other damage, and for various therapeutic purposes, such as frostbite or hyperthermia treatment, treatment of poor blood circulation, physical therapy, stimulation of collagen, cellulite treatment, adrenergic stimulation, wound healing, psoriasis treatment, body reshaping, non-invasive wrinkle removal, etc. The heating of tissues has also been utilized as a potential treatment for removing cancers or other undesired growths, infections and the like. Heating may be applied over a small localized area, over a larger area, for example to the hands or feet, or over larger regions of tissue, including the entire body.

Since most of the techniques described above involve applying energy to tissue at depth through the patient's skin surface, peak temperature generally occurs at or near the patient's skin surface and decrease, sometimes significantly, with depth. Further, while microwaves or ultrasonic and other acoustic radiation have been used in the past for certain heating treatments at depth, as disclosed in, for example, U.S. Patent No. 5,871,524 to Knowlton, U.S. Patent No.

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5,769,879 to Richards, *et al.*, U.S. Patent No. 5,507,790 to Weiss, or U.S. Patent No. 5,143,063 to Fellner, since such radiation, particularly microwaves, are potentially mutagenic and can otherwise result in cell or systemic damage and, particularly for acoustic sources, are relatively expensive, and may not be practical for large-area treatment, these techniques have had limited use for the heating of tissues.

While optical and near infrared (NIR) radiation (collectively referred to hereinafter as “optical radiation” is generally both less expensive and, being non-mutagenic, safer than microwaves radiation, the use of optical radiation has heretofore not been considered suitable for most applications involving heating of tissue at depth, the term “tissue at depth” as used herein meaning tissue at the border zone of the dermis and hypodermis, some of which tissue may be in the lower dermis, mostly at a depth deeper than 1 mm, and tissue below this border zone to a depth of up to about 50 mm The reason why this radiation has not been considered suitable is because such radiation is both highly scattered and highly absorbed in surface layers of tissue, precluding significant portions of such radiation from reaching the tissue regions at depth to cause heating thereof. In view of the energy losses due to scattering and absorption, substantial optical (including NIR) energy must be applied in order for enough such energy to reach a region of tissues at depth to have a desired effect. However, such high energy can cause damage to the surface layers of tissue, making it difficult to achieve desired photothermal treatments in tissue regions at depth. For these reasons, optical radiation has heretofore had at most limited value for therapeutic and cosmetic treatments on tissue at depth.

Further, while heating of tissue at depth alone is useful for many treatments, there are treatments, for example to relieve pain and stiffness in muscles or joints, where heating in conjunction with massage or other mechanical stimulation, ultrasound or other acoustic stimulation or electrical stimulation of the tissue may also be useful.

Thus, a need exists for improved method and apparatus for photothermal treatment of tissue regions at depth, and in particular for treatment of subdermal regions of tissue, and for method and apparatus for combining heating with stimulation in such regions for various treatments.

SUMMARY OF THE INVENTION

The present invention generally relates to methods and apparatus for photothermal treatment, both therapeutic and cosmetic, of tissue located at depth in a patient’s body, as this term has previously been defined. Optical radiation utilized in practicing the invention is at a

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wavelength or wavelength band which is neither highly scattered in the patient's skin nor highly absorbed by water in tissue so that the maximum quantity of such radiation can reach the treatment region at depth. The wavelength utilized typically is between about 600 nm and about 1850 nm, more preferably between about 800 nm and about 1350nm, and most
5 preferably between about 1050 nm and about 1250 nm. Other potential ranges for certain depths of tissue are set forth in Table 1. The longer the wavelength, the lower the scattering; however, outside of the indicated bands, water absorption is so high that little radiation can reach tissue at depth. While the tissue to be treated may be a chromophore at the wavelength(s) utilized within the above bands, this is not a limitation on the invention, and
10 absorption by water, and to a lesser extent fat or lipid, in the region is generally sufficient to achieve the desired heating. In some applications, absorption at certain wavelengths can be increased by delivering a suitable chromophore to the treatment region. The optical radiation source utilized may be a monochromatic source, such as a laser or light emitting diode (LED), or may be a wide spectrum source such as a halogen lamp or arc lamp. Where a wide spectrum
15 source is used, filtering or shifting of wavelengths outside the above bands may be performed. The source may also be a pulsed source or a continuous wave (CW) source. Natural light sources such the sun can also be used to practice this invention. Where the source is a pulsed source, the source typically remains over a treatment region for the duration of each pulse, or a train of pulses may be applied. Where the source is a (CW) source, it is typically moved over
20 the surface of the patients skin at a selected rate, the rate of movement determining the dwell time over a given treatment region.

The invention also requires that cooling be applied to the patient's skin surface concurrently with the application of optical radiation thereto. While the radiation reaches the tissue at depth to be treated quickly to begin the heating thereof, cooling propagates as a cold
25 wave protecting tissue above the treatment region and moving the depth of maximum heating further into the skin. Ideally the cooling wave propagates to a depth just above the treatment region, but does not extend to the treatment region at least until sufficient energy has been delivered to the treatment region to effect the desired treatment. Cooling may also be applied to the patient's skin prior to the application of radiation thereto to more effectively protect tissue
30 above the treatment region and to more rapidly result in maximum heat being at or near the desired depth. This may also permit higher energy and shorter duration for the radiation source. The head used to apply the radiation may also be used to apply cooling.

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Another feature of the invention is that the radiation is applied at low power for an extended time, the time varying with the depth of treatment and with the treatment being performed. For example, the time may vary from approximately 2 seconds to approximately 2 hours for depths of approximately 1 mm to 50 mm respectively. Depending on depth, the treatment being performed and other factors, the power density may vary from approximately 0.2 to 50 W/cm², more preferably from approximately 0.5 to 20 W/cm², and most preferably from 0.5 to 10 W/cm² or 0.5 to 5 W/cm².

Other advantages, novel features, and objects of the invention will become apparent from the following detailed description of the invention when considered in conjunction with the accompanying drawings, which are schematic and which are not intended to be drawn to scale. In the figures, each identical, or substantially similar component that is illustrated in various figures is represented by a single numeral or notation. For purposes of clarity, not every component is labeled in every figure, nor is every component of each embodiment of the invention shown where illustration is not necessary to allow those of ordinary skill in the art to understand the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting embodiments of the present invention will be described by way of example with reference to the accompanying drawings in which:

Fig. 1 is a schematic diagram of one embodiment of the invention, as applied to a tissue sample;

Fig. 2 is a schematic diagram of another embodiment of the invention, showing an internal design configuration;

Fig. 3 is a schematic diagram of another embodiment of the invention, showing another internal design configuration;

Fig. 4 is a schematic diagram of another embodiment of the invention, showing another internal design configuration;

Fig. 5 is a schematic diagram of another embodiment of the invention, showing another; internal design configuration

Fig. 6 is a schematic diagram of another embodiment of the invention, showing another internal design configuration;

Fig. 7 is a schematic diagram illustrating a plurality of devices of the invention being used in conjunction with each other;

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Fig. 8 is a schematic diagram of another embodiment of the invention, showing yet another internal design configuration;

Fig. 9 is a schematic diagram of another embodiment of the invention having a different configuration;

5 Fig. 10 is a schematic drawing of a model of tissue, used in certain calculations;

Fig. 11 is a plot of the temperature produced by an embodiment of the invention in a tissue sample versus tissue depth;

Fig. 12 is a plot of a temperature relaxation profile produced by an embodiment of the invention in a tissue; and

10 Fig. 13 is a plot of depth of heating vs. treatment time as determined using Equation 12.

DETAILED DESCRIPTION

Applications in which the invention may be useful include the treatment of various diseases, particularly, cellulite and subcutaneous fat treatment, physical therapy, muscle and skeletal treatments, including relief of pain and stiffness for muscles and joints, and treatment of spinal cord problems, and treatment of cumulative trauma disorders (CTD's) such as carpal tunnel syndrome (CTS), tendonitis and bursitis, fibromyalgia, lymphedema and cancer therapy.

More specifically with respect to cancer therapy, hyperthermia resulting from utilizing the teachings of this invention may be utilized to treat various skin cancers including, but not limited to, basal cell carcinoma, squamous cell carcinoma, lymphoma and possibly treatment (palliative) of melanoma. Hyperthermia may also enhance the efficacy of radiation, for example x-ray, therapy, chemotherapy, therapy with immunomodulators such as ALDARA or PDT therapy. Such combination therapy may for example reduce required treatment time.

The tissue to be treated may be a collagen-rich tissue. Collagen-rich tissues that may be treated include superficial cortical bone, synovium joint capsules, tendon sheaths, menisci, myofascial interfaces, periosteum, fibrotic muscle, or major nerve trunks. The device may also be used for reshaping procedures such as non-invasive wrinkle removal through stimulation of collagen production in a subsurface region of tissue. Heating of the subsurface region of tissue to a temperature of between 37.5 and 45 °C may stimulate generation of new collagen and/or elastin. For example, expression of HSP70 ("Heat Shock Protein") may be stimulated when the tissue is heated to between 41 and 42 °C for between 20 and 30 minutes. Other proteins, cytokines and/or growth factors may also be stimulated or released in response to heating. Significant new collagen deposition, formation or rearrangement may be possible, which may

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improve skin appearance or texture, allowing wrinkles, fine lines, scars, stretch marks or other indicators to be removed. In general, there exists a relation between the temperature reached and the time of application that is necessary to stimulate new collagen deposition and prevent irreversible damage. Additionally, multiple treatments may be used in some treatment modalities.

Hypothermia resulting from utilizing the teachings of this invention may also be utilized for hair growth management, and for treatment of psoriasis, scars, rosacea and various conditions of toe and finger nails. For hair growth management, which includes temporary and permanent hair removal and control of hair growth, a dermal or subdermal temperature rise of a few degrees, for example to 42-45° C can produce an anagen effluvium. This could be particularly useful for hair growth management on hairs containing little or no melanin, for example gray, white or blond hairs. The efficacy of such treatment may be enhanced by using wavelengths absorbed by melanin or by performing the treatment in conjunction with other hair removal techniques. Hypothermia may also be used to treat psoriasis, including psoriasis plaques and nail psoriasis. The teachings of this invention may thus be used to treat psoriasis, either alone or in conjunction with drug treatment, light treatment, for example with an excimer laser, flashlamp, uv or pulse dye laser, or other existing treatment. Scars, having different crosslinking and different denaturation thresholds than normal tissue, may be treated by hypothermia to, for example, reduce turnover, turnover being significantly enhanced for scar tissue. A special handpiece with an aperture adjustable to the shape of the scar may be desirable for treating scars. Hypothermia induced in accordance with the teachings of the invention may also be used to kill demodex mites resident in follicles which cause rosacea. Finally, hypothermia induced by this invention may be used to enhance or control growth rate of toe or finger nails or to otherwise treat conditions of these nails, for example nail fungus and dystrophic nails. The nail (matrix) is relatively accessible to light treatment. The nails can be cooled by emergence in a water bath and exposed to the light. The mechanism for enhanced nail growth may be enhanced metabolism, blood supply (vasodilation by heat and light) or biostimulation.

The application of thermal energy to tissue may also be used, for example, in physical therapy treatments, such as to enhance or accelerate wound healing or relieve pain. Beneficial effects may include a decrease in joint stiffness, an increase in joint extensibility of collagenous structures such as tendons and scar tissue, pain relief, blood-flow changes, or a decrease in muscle spasm and increase in muscle tone. As another example, large protein

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molecules may have high absorption coefficients, and the heating of protein-rich collagenous tissues may contribute to healing. A wide variety of conditions may be treated using this invention, for example, but not limited to, strained tendons, tenosynovitis, torn ligaments, tendonitis, bursitis, torn joint capsules, or torn muscles. As yet another example, other
5 processes may be activated or deactivated within the tissue during heating. For example, heating of the tissue may be used to enhance or modify the activity of a pharmaceutical or another bioactive substance or to facilitate the delivery thereof through the skin. Mechanical or electrical stimulation, such as massage, may be used in conjunction with heating to achieve benefits greater than can be achieved by either alone. Pressure may also be applied to the skin
10 surface above the treatment region to facilitate the treatment.

In another example, when tissue is heated to greater than the damage temperature of the tissue, irreversible changes to the tissue may occur, up to and including cell death, apoptosis or the like. The damage temperature is the temperature by which cells, collagen, or other tissue components may be irreversibly damaged. The damage temperature may be useful in certain
15 therapeutic situations, for example, to damage unwanted cells or other structures, such as collagen, malignant or benign tumors, hair bulb, deep pigmented lesions or fat. Further, by heating tissue to a temperature above the body temperature (typically 37°C), but below the damage temperature, it may be possible to change the dynamics of various biological processes, such as metabolism.

Where the tissue is a tumor, it may be desired to use heat in accordance with the teachings of this invention to kill the tumor, or at least a portion thereof, such as a necrotic center. Where the tissue is an artificially created tissue, such as a tissue-engineered scaffold, preferential heating of the center of the artificial tissue may be used, for example, to stimulate cell division within the tissue, to promote cell division or cell growth within the artificial tissue
25 structure.

In certain embodiments, the present invention may be used for non-invasive or non-destructive reduction of localized fat deposits. For example, the invention may be used to heat fat or adipose cells past their damage temperature, causing cell damage and/or necrosis. Alternatively, the treated cells may undergo apoptosis, resulting in cell death. The dead cells
30 may then be removed or resorbed into the body, for example, by the body's phagocytic or lymphatic systems. Fat reduction may also be achieved by heating fat or adipose cells to an elevated temperature, but below the damage temperature. For example, the fat cells may be heated to a temperature of between about 41°C and about 45°C. Under these conditions,

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applying heat to subcutaneous fat may activate lipases or metabolize lipids contained within the adipose tissue found within the subcutaneous fat layer, or blood flow may increase to the heated area. Additionally, "lipolysis," or the process of breaking down fat in the body, may be regulated by enzymes sensitive to temperature, such as HSL ("hormone-sensitive lipase").

- 5 Thus, elevating the temperature of the adipose cells may increase the lipolysis rate, and thus contribute to a reduction in subdermal fat in the area being treated. This temperature can be below the temperature for vascular/lymph damage so damaged fatty cells and fatty acids can be easily removed from the treatment region. Additionally, application of the present invention may be used in combination with other fat-reduction techniques, such as medication, exercise,
- 10 or adrenergic stimulation. Heating of subcutaneous fat may also result in increased dermal thickness. Thus, fatty tissue may be replaced by fibrous and dermal tissue, this resulting in improved skin appearance.. Thermal activation of lymph systems in subcutaneous fat can also be used to treat cellulite by removing proteins from extra cell spaces.

Stated another way, fat and/or cellulite reduction may be achieved utilizing the

15 teachings of this invention by providing an elevated (but below damage threshold ~ 43-48°C) temperature in the targeted region at depth. The mild hyperthermia initiates biological response through one or several of the following pathways:

1. Increase of activity of enzymes regulating the process of lipolysis, in particular, hormone sensitive lipase (HSL). As a result, decrease of fat stores in hypodermis.
- 20 2. Stimulation of blood and lymph flow in the targeted area with multiple positive consequences, including (but not limited to) further decrease in the fat stores and accelerated regeneration of connective tissue.
3. Induction of apoptosis in adipocytes, with subsequent removal of residual cell material by the body's scavenging system.
- 25 4. Decrease of lipid's viscosity, resulting in increasing mobility of fat globules and permeability of adipocytes' membranes.
5. Stimulation and or reorganization of the connective tissue surrounding subdermal fat depots with or without concurrent changes of the dermal collagen.

The net result is a shift of balance between fat and connective tissue in hypodermis

30 toward the latter and improved appearance of skin.

Fig. 1 shows an apparatus 100 for one embodiment of the invention. For this apparatus, optical energy 30 from a suitable energy source 1 passes through optical (for example,

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focusing) device 2, filter 3, cooling mechanism 4 and contact plate 8, before reaching tissue 31. A suitable optical impedance matching lotion or other suitable substance would typically be applied between plate 8 and tissue 31 to provide enhanced optical and thermal contact. Tissue 31, as shown in Fig. 1, is divided into an upper region 5, which, for applications where radiation is applied to the skin surface, would be the epidermis and dermis, and a lower region 6 which would be a subdermal region in the previous example. Energy 30, possibly in conjunction with one or a combination of focusing from optical device 2, and wavelength selection from filter 3, and with cooling from mechanism 4, results in maximum heating occurring at a selected depth in tissue 31, which depth is, as previously indicated, at or near the junction of regions 5 and 6 or in lower region 6 for this invention. In some embodiments of the invention, certain of these components, such as, for example, filter 3 where a monochromatic source is utilized or optics 2, may not necessarily be present.

In some embodiments of the invention, energy source 1, optical device 2 and/or filter 3 may also require a cooling mechanism. This cooling mechanism may or may not be the same as or connected to cooling mechanism 4 that cools tissue 31 through contact plate 8, as indicated by arrows 32 in Fig. 1. For example, in the embodiment shown in Fig. 1, cooling mechanism 7, shown separately from cooling mechanism 4, is used to cool filter 3. Energy source 1 may be any suitable optical energy source able to produce optical energy 30 at a wavelength that produces heating within tissue 31 at the depth of a desired treatment region. The exact energy source, and the exact energy chosen, may be a function of the tissue 31 to be heated, the depth within the tissue at which treatment is desired and of the absorption of that energy in the desired area to be treated. For example, energy source 1 may be a radiant lamp, a halogen lamp, an incandescent lamp, a arc lamp, a fluorescent lamp, a light emitting diode, a laser (including diode and fiber lasers), the sun or other suitable optical energy source.

Energy source 1 may produce electromagnetic radiation, such as near infrared or visible light radiation over a broad spectrum, over a limited spectrum or at a single wavelength, such as would be produced by a light emitting diode or a laser. In certain cases, a narrow spectral source may be preferable, as the wavelength(s) produced by the energy source may be targeted towards a specific tissue type or may be adapted for reaching a selected depth. In other embodiments, a wide spectral source may be preferable, for example, in systems where the wavelength(s) to be applied to the tissue may change, for example, by applying different filters, depending on the application.

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As previously indicated, in order to minimize both scattering and absorption of the applied optical radiation, the optical radiation produced by energy source 1 should be radiation with a wavelength which is minimally scattered and absorbed, the available wavelengths decreasing with increasing depth as generally indicated in Table 1.

5 Certain wavelengths may be preferentially absorbed by the tissue to be treated. As one example, if the tissue to be treated includes subcutaneous fat, certain wavelengths may be absorbed more effectively by the fat or adipose cells than by the surrounding tissues. For example, optical radiation having wavelengths around 925 nm, 1206 nm, 1730 nm and 2300 nm may be desirable (see for example copending application serial #09/277307, which is
10 incorporated herein by reference, for suitable ranges); however, only the lower three of these ranges would typically provide sufficient penetration for use in practicing this invention. Using electromagnetic radiation of these wavelengths, the coefficient of absorption by this radiation in the lipids, and in particular the triglycerides located within the adipose tissue may be greater than that of the absorption coefficient of these wavelengths in water. Thus, these
15 wavelengths when applied to a tissue sample, will preferentially be absorbed by the fat tissue, thus resulting in the preferential heating of this tissue. The selective heating of the fatty tissue can be enhanced by the lower heat capacity of fatty tissue vs. aqueous tissue. Also, the decreased blood perfusion of the subcutaneous fat vs. the dermis can be used to enhance selective heating of the fatty tissue. Compression sufficient to reduce blood flow within the
20 target area can minimize unwanted heat convection, and therefore heat leakage, from the target area. The compression to the subdermal target area can be made selective by forming a skin fold and applying skin pressure sidewise. This results in compression of the subcutaneous fat and of skin outside the field of optical exposure. The skin on top of the skin fold, which skin is exposed to the optical radiation, is not compressed, and therefore the blood flow therein is
25 not appreciably reduced so long as the length of the skin fold does not exceed a critical length. Blood flow within the part of the dermis exposed to optical radiation can help to remove unwanted excessive heat in this skin component.

Where optical device 2 is a focusing device, it may be any suitable device able to focus at least a portion of energy 30 arriving from energy source 1 at tissue 31, and in particular at a
30 selected depth in tissue 31. For example, device 2 may include mirrors, prisms, reflectors, lenses such as Fresnel lenses, collimating lenses or focusing lenses, diffraction gratings, or other optical device.

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Filter 3 may be any suitable filter able to select, or at least partially select, certain wavelengths or wavelength bands from energy source 1. In certain types of filters, a specific set of wavelengths may be blocked by the filter. It is also possible that undesired wavelengths in the energy from source 1 may be wavelength shifted in ways known in the art so as to
5 enhance the energy available in the desired wavelength bands indicated above and in Table 1. Thus, filter 3 may include elements designed to absorb, reflect or alter certain wavelengths of electromagnetic radiation. For example, filter 3 may be used to remove certain types of wavelengths that are absorbed by surrounding tissues. For instance, dermis and epidermis tissues are primarily composed of water, as is much of the rest of the human body. By using a
10 filter that selectively removes wavelengths that excite water molecules, the absorption of these wavelengths by the body may be greatly reduced, which may contribute to a reduction in the amount of heat generated by light absorption in these molecules. Thus, by passing radiation through a water-based filter, those frequencies of radiation which may excite water molecules will be absorbed in the water filter, and will not be transmitted into tissue 31. Thus, a water-
15 based filter may be used to decrease the amount of radiation absorbed in tissue above the treatment region and converted into heat.

In other embodiments, filter 3 may be combined with other elements of the device, for example, cooling system 4 or cooling mechanism 7. Thus, water may both attenuate energy 30 arising from energy source 1, as well as cool the contact plate, and tissue in contact with the
20 contact plate, or various other components of the device. More than one filter or filter type may also be present.

Fig. 1 shows a cooling mechanism 4 adjacent to the surface of tissue 31. Cooling mechanism 4 may be any suitable cooling mechanism able to reduce the temperature of tissue 31. Heat energy 32 may be drawn from tissue 31 across contact plate 8 into cooling
25 mechanism 4. For example, cooling system 4 may be air or other suitable gas that is blown over contact plate 8, cooling water, or a cooling oil or other fluid. Mixtures of these substances, such as an oil and water mixture, may also be envisioned. Cooling mechanism 4 may have any suitable configuration, for example, a flat plate, a series of conducting pipes, a sheathing blanket, or a series of channels for the passage of air, or other gases, or liquid across
30 plate 8. For example, in one embodiment, cooling system 4 may be a water-cooled contact plate. In another embodiment, cooling mechanism 4 may be a series of channels carrying a coolant fluid or a refrigerant fluid (for example, a cryogen), which channels are in contact with tissue 31 or with plate 8. In yet another embodiment, cooling system 4 may comprise a water

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or refrigerant fluid (for example R134A) spray, a cool air spray or air flow across the surface of tissue 31. In other embodiments, cooling may be accomplished through chemical reactions (for example, endothermic reactions), or through electronic cooling, such as Peltier cooling. In yet other embodiments, cooling mechanism 4 may have more than one type of coolant, or
5 cooling mechanism 4 and/or contact plate 8 may be absent, for example, in embodiments where the tissue is cooled passively or directly, for example, through a cryogenic or other suitable spray. Sensors or other monitoring devices may also be embedded in cooling mechanism 4, for example, to monitor the temperature, or determine the degree of cooling required by tissue 31, and be manually or electronically controlled.

10 In certain cases, cooling mechanism 4 may be used to maintain the surface temperature of tissue 31 at its normal temperature, which may be, for example, 37 or 32 °C, depending on the type of tissue being heated. In other embodiments, cooling mechanism 4 may be used to decrease the temperature of the surface of tissue 31 to a temperature below the normal temperature of that type of tissue. For example, cooling mechanism 4 may be able to decrease
15 the surface temperature of tissue 31 to, for example, a range between 25 °C and -5 °C.

In some embodiments of the invention, such as shown in Fig. 1, energy 30 from energy source 1 may pass through cooling mechanism 4. In these types of configurations, cooling mechanism 4 may be constructed out of materials able to transmit at least a portion of energy 30, for example, air, water or other gases or fluids, glass, or a clear plastic. In other
20 embodiments, cooling mechanism 4 may be formed out of a series of discrete channels, and energy 30 may pass between these channels. In other embodiments of the invention, energy 30 may not be directed through cooling mechanism 4. For example, in the embodiment shown in Fig. 8, energy source 19 and cooling system 18 may be positioned on opposite sides of chamber 17.

25 Contact plate 8 may be made out of a suitable heat transfer material, and also, where the plate contacts tissue 31, of a material having a good optical match with the tissue. Sapphire is an example of a suitable material for plate 8. In some embodiments, contact plate 8 may have a high degree of thermal conductivity, for example, to allow cooling of the surface of the tissue by cooling mechanism 4. In other embodiments, contact plate 8 may be an integral part
30 of cooling mechanism 4, or be absent. Contact plate 8 may be made out of a deformable or viscoelastic material in some embodiments of the invention, for example, a gel such as a hydrogel. In other embodiments, contact plate 8 may be made of a solid material, such as a glass, a crystal such as sapphire, or a plastic. In some embodiments of the invention, such as

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shown in Fig. 1, energy 30 from energy source 1 may pass through contact plate 8. In these configurations, contact plate 8 may be constructed out of materials able to transmit at least a portion of energy 30, for example glass, sapphire, or a clear plastic, or contact plate 8 may be constructed in such a way as to allow at least a portion of energy 30 to pass through contact plate 8, for example, via a series of holes within contact plate 8.

In certain embodiments of the invention, various components of system 100 may require cooling. For example, in the embodiment shown in Fig. 1, optical device 2 and filter 3 may be cooled by cooling mechanism 7. The design of cooling mechanism 7 may be a function of the components used in the construction of the apparatus. Cooling mechanism 7 and cooling mechanism 4, in Fig. 1, are illustrated as separate systems. However, in other embodiments, cooling mechanism 7 and cooling mechanism 4 may be part of the same system, or one or both may be absent. Cooling mechanism 7 may be any suitable cooling mechanism known in the art, such as air, water, or an oil. Mixtures of these substances, such as an oil and water mixture, may also be envisioned. Cooling of the components may be accomplished through convective or conductive cooling.

One or more of energy source 1, optical device 2, filter 3, cooling mechanism 4, or cooling mechanism 7 may be electronically controlled. For example, sensors embedded in cooling mechanism 4 or contact plate 8 may determine the amount of energy reaching tissue 31, and may direct energy source 1 to produce more or less energy or may direct cooling mechanism 4 to increase or decrease cooling, depending on the application. Other sensors and the like may be embedded in any of the components illustrated herein. The controls may be, for example, electronically preprogrammed, or manually operable.

The present invention is not limited to treating a specific region or area of tissue. For example, as illustrated in Figs. 8 and 9, the invention may be constructed in such a way as to treat an entire person. For example, in Fig. 8, chamber 17 contains cooling mechanism 18 and energy source 19. Cooling mechanism 18 may be cooled in the same ways described above for cooling mechanisms 4 and 7. Energy source 19 may contain, for example, a series of lamps or other energy sources, optionally surrounded by filters 40. In this embodiment, filters 40 are built into the side of chamber 17. Fig. 9 shows another design, where chamber 17 has a cooling mechanism 18, but does not contain an energy source. Instead, energy 42 from the sun 41 or another energy source, such as an external lamp, is directed to chamber 17, for example, directly, by means of reflectors 20, or by means of a lens such as Fresnel lens 19. The patient may be cooled within the chamber by air flow or other suitable cooling mechanism 18.

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In Fig. 2, another embodiment of the invention is shown. In this embodiment, a lamp 9, for example an incandescent lamp, is used as the energy source. Lamp 9 is surrounded by a specially coated reflector 10 to maximize light delivery efficiency to the treatment region of tissue 31. A fluid 13 may pass between contact plate 8 and filter 3. Contact plate 8, cooled by
5 fluid 13, may cool the surface of the tissue to which it is applied. In Fig. 3, lamp 9 has been replaced by a monochromatic light emitting element 11 and lens 12, element 11 being, for example a laser diode, other suitable laser or a light emitting diode. As in the embodiment shown in Fig. 2, contact plate 8 and filter 3 are cooled by fluid 13 flowing therebetween; these two components may also be cooled by flow of cold liquid gas, for example R134A, from a
10 pressurized can. Thus, this embodiment illustrates how a monochromatic element 11 may be used as the energy source.

A different type of cooling mechanism is illustrated in Fig. 4. In Fig. 4, energy arising from energy source 1 is reflected using reflector 10 through filter 3, a transparent isolating material 16, and contact plate 8. Two fluids are used to cool the filter and the contact plate.
15 Upper fluid 14 flows between filter 3 and isolating material 16, while lower fluid 15 passes between isolating material 16 and contact plate 8. Fluids 14 and 15, in this embodiment, may not be the same fluid; however, in other embodiments, the two fluids may be the same fluid, or have a common reservoir. Contact plate 8, in this embodiment, may be made out of, for example, a transparent or a semi-transparent material, such as a glass, plastic or sapphire.
20 Alternatively, contact plate 8 may be formed out of an opaque material, but have openings to allow energy to pass through contact plate 8. A similar embodiment of the invention is shown in Fig. 5, where the energy source 1 has been replaced by an element that produces discrete wavelengths, such as a light emitting diode or a laser diode 11. Optional lens 12 has also been added to the system as illustrated in Fig. 5.

In certain embodiments of the invention, contact plate 8 may be absent. For example, in the embodiment shown in Fig. 6, no contact plate is used, and fluid 13 (for example a liquid, gas such as air or a spray) passes or flows directly over the surface of tissue 31. Legs 42
25 connected to the device may be constructed in such a manner as to correctly position filter 3 over the surface of the tissue. Legs 42 may be any component able to maintain a proper distance between the surface of tissue 31 and device 100. In some embodiments of the invention, legs 42 may be constructed out of a flexible or a semi-solid substance that, for example, may conform to the surface of tissue 31, such as a gel. In other embodiments of the invention, legs 42 may be constructed out of a solid substance, such as rubber or plastic. Legs
30

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42 may have any arrangement underneath the device that allows for the proper positioning of the device relative to the tissue. For example, legs 42 may be arranged in a triangular or a square pattern. In other embodiments of the invention, legs 42 may be a ring or a series of bars that surrounds the area being treated or legs 42 may be absent.

5 More than one device 100 of this invention may be used simultaneously. For example, in Fig. 7, a series of devices 100 have been arranged into a semicircular pattern. These devices may be linked together to treat large areas of a subject's body. Additionally, the devices may be interconnected in such a way as to provide flexibility, so that, for example, the apparatus may conform to the contours of the body. For example, the device may be worn as a belt, a leg
10 wrap, an arm wrap, or wrapped around the torso. Devices 100 may also be mounted to a chair, bed or other suitable surface for the treatment of a patient's back, thighs and/or buttocks. Alternatively, devices 100 may be used to create an array of small island areas within a larger area (see for example copending application serial 10/033,302 which is incorporated herein by reference). This may, for example, be a safer alternative to large area heating, particularly for
15 extended treatment regimens. By optimizing the spacing between treated areas, for example, through the addition of "masks" in filter 3 between energy source 1 and tissue 31 that block portions of the energy arising from energy source 1, and/or through the use of multiple separate devices 100 as is shown in Fig. 7, treatment of the subdermal tissue may be maximized, while causing a minimal amount of patient discomfort, and/or allowing faster recovery time.

20 Where optical source 1 is a continuous wave (CW) or other long duration source, device 100 for various of the embodiments may be slid or scanned over the surface of the patient's skin to overlie successive treatment regions, the dwell time, and thus the treatment duration, for each such region being a function of the rate at which the device is moved. The device may also include a cooling mechanism ahead of the portion of the device
25 under source 1 to precool skin above the treatment region (see for example issued U.S. Patents Nos. 6,273,884 and 6,511,475, which are incorporated herein by reference).

Any of the embodiments can include a contact sensor to assure good optical and thermal coupling, and systems operating in the sliding mode may also include one or more motion sensors to control radiation delivery, cooling and other functions dependent on
30 scanning speed, to enhance system safety and for other reasons.

In addition to coupling the deep heating treatment of this invention with deep cooling to enhance treatment of fat, bone, muscle, etc., device 100 may also include a massager, vibrator or other mechanical stimulation device or a DC or other suitable electrical stimulation source.

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It has been found that such mechanical or electrical stimulation is more effective for hot tissue. Similarly, the effect of deep heating may be enhanced by massage or other stimulation because both heat and cold generally penetrates better in compressed skin and subdermal tissue. Thus, the combination of deep heating and mechanical or electrical stimulation may provide

5 significantly better results than either one alone. Heating may also be enhanced by supplementing the optical heating with, for example electro-stimulation by AC/DC, or additional heating by RF, etc. Tensioning or pressure applied to the skin overlying the treatment region may also enhance treatment effect.

The teachings of this invention may also be utilized for hair removal treatments by

10 targeting the hair bulb, which is generally located in the subcutaneous layer 6. The treatment would be done at low power sufficient to raise the temperature of the fat surrounding the hair bulb, and thus the hair bulb, to roughly 45°C and should be performed for a relatively long time period, for example, 15 minutes. The hair bulb also contains high proliferation water cells which react strongly with the applied radiation to increase bulb temperature, leading to the

15 destruction thereof.

The function and advantages of these and other embodiments of the present invention will be more fully understood from the following examples. These examples are intended to be only illustrative in nature and are not intended to limit the scope of the invention.

20 **Example 1**

This example illustrates theoretical calculations corresponding to one embodiment of the invention as applied to human skin.

Initially, a model of the skin was prepared. This model included two layers of tissue possessing distinct optical and thermal properties: dermis and subcutaneous fat (Fig. 10). The

25 presence of fine structures such as the basal layer and the vessel plexus was neglected. Monochromatic light was assumed to be incident normal to the surface. The input power density was designated as F_0 . Both the surface temperature (T_s) at depth $z=0$ and the bottom temperature (T_h) at depth $z=h$ were kept fixed at prescribed levels. Specifically, T_h was set at 37 °C due to the temperature stabilization effect of blood and metabolic heat generation on

30 muscle tissue. The objective of this example was to evaluate the steady-state temperature distribution within the skin and to find the characteristic depth z_{\max} where the steady-state temperature reaches a maximum.

Starting with the problem of light transport within the tissue, scattering in both tissue layers predominated strongly over absorption, allowing the diffuse approximation to be applied. This approach was particularly valid within the wavelength range of 600 nm to 1400 nm, which may also be referred to as the “therapeutic window”. The one-dimensional light transport problem in the diffusion approximation for the two-layered tissue model of Fig. 10 can be solved assuming both the tissue irradiance and the light flux to be the continuous functions of coordinate z at the dermis and fat interface. The resulting expression for the tissue irradiance, ψ , obtained may be written in the following general form:

$$(1)$$

$$\begin{aligned} \psi_1(z) &= F_0 \cdot \tau_{col} \cdot [V_1 \cdot \exp(-\kappa_1 \cdot z) + V_2 \cdot \exp(\kappa_1 \cdot z) - V_3 \cdot \exp(-\mu t_1 \cdot z)], \quad z \leq h_d, \\ \psi_2(z) &= F_0 \cdot \tau_{col} \cdot [V_4 \cdot \exp(-\kappa_2 \cdot (z - h_d)) - V_5 \cdot \exp(-\mu t_2 \cdot (z - h_d))], \quad z > h_d \end{aligned}$$

where indices 1 and 2 stand for dermis and subcutaneous fat, respectively. $\kappa = \sqrt{3 \cdot \mu_a \cdot \mu_r}$ and $\mu t = \mu_a + \mu_s$ are the diffusion and extinction coefficients for light in the corresponding

layers, and $\tau_{col} = \frac{4n_1n_2}{(n_1 + n_2)^2}$ is the attenuation coefficient of the collimated light at the surface. Flux amplitudes V_1 to V_5 were determined by the boundary and interface conditions. In particular, if the coefficients of refraction of both layers are the same, the interface condition at $z = h_d$ is such that both the radiance and the total light flux should be continuous functions of depth.

Turning to the problem of heat conduction within the two-layered tissue model, the time dependent equation of heat conduction in the k -th layer was:

$$\frac{\partial}{\partial t} T(z, t) = \alpha_k \frac{\partial^2}{\partial z^2} T(z, t) + Q_k(z, t), \quad (2)$$

yielding the following steady-state equation:

$$\alpha_k \frac{d^2}{dz^2} T(z) = -Q_k(z), \quad (3)$$

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where α_k was the thermal diffusivity of the k -th layer ($k = 1, 2$). The heat source term Q_k in these equations describes the generation of heat due to light absorption in the tissue. In the steady-state case, the source term is:

$$Q_k(z) = \frac{\mu_{ak}}{\rho_k \cdot c_k} \cdot \psi_k(z), \quad (4)$$

where μ_{ak} , ρ_k and c_k are the coefficient of absorption, density, and specific heat of the k -th layer, respectively.

Boundary conditions were assumed to be $T(0) = T_s, T(h) = T_h$. The solution of Equation (3) was then found to be:

$$T_2(z) = T_h + B \cdot (h - z) - \frac{1}{\alpha_2} \cdot \int_z^h dz' \int_{hd}^{z'} dz'' Q(z''),$$

$$T_1(z) = T_s + A \cdot z - \frac{1}{\alpha_1} \cdot \int_0^z dz' \int_0^{z'} dz'' Q(z''), \quad (5)$$

where parameters A and B have to be found from the interface conditions. For the case of perfect thermal contact:

$$T_1(h_d) = T_2(h_d),$$

$$k_1 \frac{d}{dz} T_1(h_d) = k_2 \frac{d}{dz} T_2(h_d), \quad (6)$$

where k_1 and k_2 are the thermal conductivities of dermis and fat, respectively.

The analytic expression for the temperature, $T(z)$, was then obtained by substituting Equation (3) into Equations (4) and (5).

A simpler expression for the temperature distribution was obtained for a homogenous medium with no layered structure. In this case, the radiance distribution took the following general form:

$$\psi(z) = F_0 \tau_{col} [\exp(-\mu_t z) + \phi_d(z)], \quad (7)$$

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where the first term was the collimated radiance and the second one was the diffuse radiance given by:

$$\varphi_d(z) = V_2 \cdot \exp(-\kappa \cdot z) - V_1 \cdot \exp(-\mu_t z). \quad (8)$$

5

The temperature distribution was:

$$T(z) = T_s + (T_h - T_s) \cdot \frac{z}{h} + F_0 \frac{V_0}{\alpha} \left\{ \frac{1 - V_1}{\mu_t^2} \cdot \left[1 - e^{-\mu_t z} - (1 - e^{-\mu_t z}) \cdot \frac{z}{h} \right] + \frac{V_2}{\kappa^2} \cdot \left[1 - e^{-\kappa h} - (1 - e^{-\kappa h}) \cdot \frac{z}{h} \right] \right\}$$

with $V_0 = \mu_a \cdot \tau_{sp} / (\rho c)$. (9)

10

Differentiating Equation (9) with respect to z yields the following implicit expression for the depth z_{\max} , the localized tissue depth at which maximum temperature occurs:

$$T_h - T_s = \frac{F_0 \cdot V_0}{\alpha} \cdot \left[\frac{1 - V_1}{\mu_t^2} \cdot (1 - e^{-\mu_t h} - \mu_t \cdot h \cdot e^{-\mu_t z_{\max}}) + \frac{V_2}{\kappa^2} \cdot (1 - e^{-\kappa h} - \kappa \cdot h \cdot e^{-\kappa z_{\max}}) \right] \quad (10)$$

15

$T_{\max} = T_h - T_s$ is maximum temperature rise in the tissue at the depth z_{\max} .

Equation (10) was solved numerically. To get an approximate analytic expression, the inequality $\mu_t \gg \kappa$ was used, which is typically valid within the therapeutic window. Then, dropping the exponential terms with μ_t , and solving the simplified equation with respect to z_{\max} yielded the following

20

$$z_{\max} = -\frac{1}{\kappa} \cdot \ln \left[\frac{\kappa \cdot (1 - V_1)}{V_2 \cdot h \cdot \mu_t^2} + \frac{1 - \exp(-\kappa h)}{\kappa h} - \frac{\alpha \kappa}{F_0 V_0 V_2 h} \cdot (T_h - T_s) \right]. \quad (11)$$

25 Maximum temperature can be calculated from (9) as $T_{\max} = T(z_{\max})$

It can be seen from these results that an increase in F_0 caused the temperature maximum to move upwards, provided the input flux is sufficiently small. At larger value of F_0 , the maximum ceased to move while proceeding to grow in amplitude. The treatment time

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should be long enough to remove heat from the layer $0 < z < z_{\max}$. This time t_{\min} was given by the formula:

$$t_{\min} = \frac{(6 \div 60) \cdot z_{\max}^3}{\alpha_1 \cdot z_1 + \alpha_2 \cdot z_2} \quad (12)$$

5 where z_1 is the depth into dermis and z_2 is depth into subcutaneous fat, and $z_1 + z_2 = z$ is depth of treatment. The numerator constant (6÷60) varies within the given range depending on how close the desired temperature is to T_{\max} , being 6 for $T_{z\max} = 90\% T_{\max}$ and 60 for $T_{z\max} = 99\% T_{\max}$. The treatment time must be longer than t_{\min} . Fig. 11 shows a typical temperature distribution in the body. Fig. 13 and Table 2 show minimum treatment time as a
10 function of depth of treatment z .

Equations (10), (11), and (12) describe a set of heating and cooling parameters that allow control of both the value and location of the internal temperature maximum. Fig. 11 shows a graph generated using these equations that shows that a broad spectral source, having a proper set of filters, combined with surface cooling, allows the temperature within the
15 adipose layer of tissue to be elevated to a maximum, while maintaining acceptable temperatures surrounding tissue and in particular, in tissue above the treatment region through which the radiation passes.

Thus, this example illustrates theoretical calculations corresponding to one embodiment of the invention.

20

Example 2

The following prophetic example illustrates treatment parameters for different body layers that may be used in one embodiment of the invention, as applied to human skin.

Based on the calculation illustrated in Example 1, treatment parameters for different
25 layers of the body that may be used in one embodiment of the invention can be determined. These calculations are summarized in Table 1. The body layers model includes the reticular dermis, dermis subcutaneous fat junction, and subcutaneous fat layer.

Using a broad-spectrum lamp in this embodiment of the invention, the treatment parameters include a surface cooling mechanism able to maintain a surface cooling
30 temperature of between 0 °C and 32 °C; a broad-spectrum lamp, where the color temperature of the lamp is between 300 K and 3000 K, with filtering of more than 50% of the light having

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wavelengths of less than 800 nm and greater than 1800 nm, preferably 900 to 1400 nm, and most preferably 1100 to 1250 nm. Depending on depth, the treatment being performed and other factors, the power may vary from approximately 0.2 to 50 W/cm², and more preferably from approximately 0.5 to 20 W/cm², with a treatment time of between 2 sec for a 1 mm depth and 7300 sec for a 50 mm depth. When operating in sliding mode, treatment power and duration increase.

Thus, this prophetic example illustrates exemplary treatment parameters that may be used to heat different layers of the body, in one embodiment of the invention.

Table 1. Typical parameters of treatment:												
Organ	Depth of peak temperature, mm	Wavelength range, μm		Treatment parameters with precooling for preferable wavelength range					Treatment parameters without precooling for preferable wavelength range			
		Maximum	Preferable	Most preferable	Cooling temperature, $^{\circ}\text{C}$	Precooling time, s	Time of treatment, s	Fluence		Cooling temperature, $^{\circ}\text{C}$	Minimum time of treatment, s	Power density, W/cm^2
								J/cm^2	W/cm^2			
Reticular dermis	1-3	0.6-1.85	0.8-1.4 & 1.5-1.8	1.2-1.3 & 1.6-1.8	5	1-30	2-40	10-200	5-30	5	2-65	2.5-50
Dermis subcutaneous fat junction	2-5	0.6-1.35 & 1.6-1.8	1.1-1.25 & 1.65-1.8	1.15-1.23 & 1.7-1.75	5	1-30	10-40	150-200	5-15	5	2-65	2.5-50
Subcutaneous fat	5-10	0.8-1.4 & 1.6-1.7	1.1-1.3 & 1.65-1.8	1.15-1.23	5	30-110	40-300	200-500	1.7-5	5	65-270 270-1100	0.5-20
	10-20	0.8-1.3	1.1-1.25	1.15-1.23		110-450	300-800	500-1000	1.2-5	5	1100-7300	0.5-10
	20-50	0.8-1.3	1.05-1.25	1.05-1.15		450-2800	800-1200	1000-1200	1-1.2	5		0.2-5

Table 2. Minimum treatment time without precooling

Depth, mm	Treatment time, sec
1	2
2	10
3	20
4	40
5	65
6	95
7	130
8	170
9	220
10	275
12	400
14	550
16	720
18	915
20	1100
25	1800
30	2600
35	3500
40	4600
45	5900
50	7300

Example 3

5 In this example, a device 100 of this invention substantially as shown in Fig.2 was used to heat subcutaneous fat in the stomach region of a volunteer. Light from a halogen lamp 9 was filtered with a combination of a short cut or high pass filter 8 with an 800 nm cut-off and a 3 mm thick water layer 41. The temperature of water 41 was 12°C, while the temperature of a sapphire plate 8 and of the skin interface was 18°C. Power density was 4W/cm² and the treatment time was 300 sec. After heating the subcutaneous fat layer for 300 sec., the device was removed, and two thermocouples were immediately implanted 1 mm and 8 mm below the skin surface under the heated region to determine the final, steady-state temperatures and to monitor the temperature relaxation profiles in the dermis and fat layer respectively.

10 Temperature data recorded by the two thermocouples are shown in Fig. 12. The initial temperature of the subcutaneous fat layer at a depth of 8 mm was found to be approximately 45 °C, while the temperature of the dermis, 1 mm below the surface of the skin, was found to be about 40 °C and the temperature at the epidermis was 24°C. Over the course of the next several minutes, the temperatures of the dermis and the subcutaneous fat layer decreased

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towards basal levels of 37 °C for the subcutaneous fat layer and approximately 32 °C for the dermis.

The same device 100 was used to perform the same test on a 25 mm bulk of pig skin and subcutaneous fat which was placed on a thermally stable plate with a temperature of 37°C.

5 The power density for this test was 10 W/cm² and cooling water having a temperature of 4°C was used. After a treatment time of 300 sec., peak temperature of 53°C was found at a depth 14 mm into the fat. The temperature at the epidermis at this time was 38°C. After about 6 weeks, this exposure setting induced reduction of subcutaneous fat without evidence for epidermal damage. A partial replacement of fatty tissue by connective collagen tissue was observed.

10 reduction of hair growth was also observed several weeks after this and similar exposure settings, even if a lower temperature rise was obtained and only a single treatment was performed. This clearly emphasized the possibility of using this method to manage unwanted hair growth. Highly proliferating cells like sebocytes within the sebaceous glands or hair matrix cells within the hair follicle are particularly sensitive to heating which can be used to

15 achieve selective effects on these structures even by unselective heating of the depth were these structures are located. Hair matrix cells are also surrounded by fatty cells and the sebaceous glands are generating lipids. The decreased heat capacity for lipids provides additional selective effects. This can also be specifically useful for the treatment of non pigmented hairs that are usually not affected by standard light assisted methods for

20 photoepilation based on selective photothermolysis. Hair growth management may include permanent or temporary hair removal or merely controlling/slowing hair growth rate.

These examples thus illustrates how a device of the invention may be used to heat a subdermal layer of tissue to a temperature significantly higher than normal body temperature and the temperature of surrounding tissue, including tissue between the skin surface and the

25 treatment region..

While several embodiments of the invention have been described and illustrated herein, those of ordinary skill in the art will readily envision a variety of other means and structures for performing the functions and/or obtaining the results and/or advantages described herein, and each of such variations or modifications is deemed to be within the scope of the present

30 invention. More generally, those skilled in the art would readily appreciate that all parameters, dimensions, materials, and configurations described herein are meant to be exemplary and that actual parameters, dimensions, materials, and configurations will depend upon specific applications for which the teachings of the present invention are used. Those skilled in the art

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will recognize, or be able to ascertain using no more than routine experimentation, many equivalents to the specific embodiments of the invention described herein. It is, therefore, to be understood that the foregoing embodiments are presented by way of example only and that, within the scope of the appended claims and equivalents thereto, the invention may be

5 practiced otherwise than as specifically described. The present invention is directed to each individual feature, system, material and/or method described herein. In addition, any combination of two or more such features, systems, materials and/or methods, if such features, systems, materials and/or methods are not mutually inconsistent, is included within the scope of the present invention. In the claims, all transitional phrases or phrases of inclusion, such as

10 “comprising,” “including,” “carrying,” “having,” “containing,” and the like are to be understood to be open-ended, i.e. to mean “including but not limited to.” Only the transitional phrases or phrases of inclusion “consisting of” and “consisting essentially of” are to be interpreted as closed or semi-closed phrases, respectively.

15 What is claimed is:

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CLAIMS

1. Apparatus for treating at least a selected region at depth of a patient while protecting tissue above the selected region, comprising:
 - 5 an optical radiation source for delivering optical radiation at a power of between 0.2-50W/cm² to the patient's skin, said power varying at least in part as a function of the depth of said selected region, said optical radiation being applied to said selected region for at least approximately 2 seconds; and
 - a cooling mechanism for cooling tissue above said selected region to a
10 temperature below that of said selected region.
2. Apparatus as claimed in claim 1 wherein said power is 0.5-20W/cm².
3. Apparatus as claimed in claim 1 wherein said power is 0.5-5W/cm².
15
4. Apparatus as claimed in claim 1 wherein said source includes a broadband optical radiation source, and a filter through which radiation from said broadband source is passed.
5. Apparatus as claimed in claim 4 wherein said filter includes a water filter to at least
20 attenuate wavelengths from said broadband source which are selectively absorbed by water.
6. Apparatus as claimed in claim 5 wherein said water filter includes chilled water flowing between said broadband source and the patient's body, said flowing chilled water also functioning as part of said mechanism for cooling.
25
7. Apparatus as claimed in claim 4 wherein said cooling mechanism also cools said filter.
8. Apparatus as claimed in claim 4 including a mechanism for removing heat from said filter.
30
9. Apparatus as claimed in claim 1 wherein said source includes optics for shaping radiation to be delivered to said selected region.

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10. Apparatus as claimed in claim 1 wherein said source is at least primarily at one or more wavelengths between about 600 nm and about 1850 nm.
11. Apparatus as claimed in claim 10 wherein said source is at least primarily at one or
5 more wavelengths between about 800 nm and about 1350 nm.
12. Apparatus as claimed in claim 10 wherein said source is at least primarily at one or more wavelengths between about 1050 nm and about 1250 nm.
- 10 13. Apparatus as claimed in claim 1 wherein said optical radiation source and said mechanism are concurrently operated for a period of at least two seconds.
14. Apparatus as claimed in claim 13 wherein said optical radiation source and said mechanism are concurrently operated for a period of at least five seconds.
- 15 15. Apparatus as claimed in claim 1 wherein said optical radiation source and said mechanism are concurrently operated for a period of between about two seconds and two hours.
- 20 16. Apparatus as claimed in claim 13 including a precooling mechanism which cools tissue above said selected region prior to the concurrent operation of said source and said cooling mechanism.
17. Apparatus as claimed in claim 16 wherein said cooling mechanism and said precooling
25 mechanism are the same mechanism.
18. Apparatus as claimed in claim 16 wherein said optical radiation power and said period of concurrent operation vary dependent on whether said precooling mechanism is operated.
- 30 19. Apparatus as claimed in claim 1 wherein parameters for said optical radiation source and for said cooling mechanism are selected to achieve a selected temperature as indicated by equation 10 at a selected depth z_{\max} determined by equation 11.

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20. Apparatus as claimed in claim 19 wherein the minimum treatment time for the apparatus is determined in accordance with equation 12.
21. Apparatus as claimed in claim 1 wherein said apparatus is an apparatus for fat
5 reduction, said radiation heating subdermal fat tissue.
22. Apparatus as claimed in claim 1 including a mechanism for stimulating tissue in said selected region.
- 10 23. Apparatus as claimed in claim 22 wherein said mechanism for providing stimulation is at least one of a mechanical stimulator, acoustic stimulator and an electrical stimulator.
24. Apparatus as claimed in claim 1 wherein said selected region contains at least one hair bulb, and wherein parameters for said apparatus, including said source, are selected to slowly
15 damage said bulb.
25. A method for treating at least a selected region at depth of a patient's body while protecting tissue above the selected region, comprising:
- 20 (a) selectively delivering optical radiation at a power between approximately 0.2 and 50 W/cm² to the patient's body above said selected region, said power varying at least in part as a function of the depth of said selected region, said optical radiation being applied to said selected region for at least approximately 2 seconds; and
- (b) concurrently cooling patient tissue above said selected region to a temperature below that of the selected region.
- 25 26. A method as claimed in claim 25 wherein said power is 0.5-20 W/cm².
27. A method as claimed in claim 25 wherein said power is 0.5-5 W/cm².
- 30 28. A method as claimed in claim 25 wherein step (a) includes generating broad band optical radiation, and filtering said broad band radiation before delivering it to said patient's body.

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29. A method as claimed in claim 25 wherein said method is a method for fat reduction, said radiation heating subdermal fat tissue.
30. A method as claimed in claim 25 wherein said method is a method for performing
5 therapy on at least one of subdermal muscle, ligament and bone, said radiation causing heating of such muscle/ligament/bone and of tissue in the area thereof to at least increase blood flow in such area.
31. A method as claimed in claim 25 wherein said method is a method for treating a
10 selected unwanted growth, said radiation heating said growth sufficiently to cause the destruction thereof.
32. The method of claim 25, wherein the electromagnetic energy is at least primarily at one or more wavelengths between about 600 nm and about 1850 nm.
- 15 33. The method of claim 32, wherein the electromagnetic energy is at least primarily at one or more wavelengths between about 800 nm and about 13500 nm.
34. The method of claim 32 wherein the electromagnetic energy is at least primarily at one
20 or more wavelengths between about 1050 nm and about 1250 nm.
35. The method of claim 25 wherein step (a) and step (b) are performed concurrently for a period of at least two seconds.
- 25 36. The method of claim 35 wherein step (a) and step (b) are performed concurrently for a period of at least five seconds.
37. The method of claim 25 wherein step (a) and step (b) are performed concurrently for a period of between about two seconds and about two hours.
- 30 38. The method of claim 25 including the step of precooling tissue above said selected region.

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39. The method of claim 38 wherein said optical radiation power and said period of concurrent operation vary dependent on whether said precooling step is performed.
40. The method of claim 25 wherein said selected region is heated during step (a).
- 5 41. The method of claim 25 wherein parameters for said optical radiation and for said cooling are selected to achieve a selected temperature as indicated by equation 10 at a selected depth z_{\max} determined by equation 11.
- 10 42. The method of claim 41 wherein the minimum treatment time for the method is determined in accordance with equation 12.
43. The method of claim 25 wherein said method is a method for fat reduction, subdermal fat tissue being heated during step (a).
- 15 44. The method of claim 25 including the step of stimulating tissue in said selected region.
45. The method of claim 44 wherein said step of providing stimulation provides at least one of mechanical stimulation, acoustic stimulation and electrical stimulation.
- 20 46. The method of claim 25 wherein said selected region contains at least one hair bulb, and wherein parameters for said method, including said radiation, are selected to slowly damage said bulb.
- 25 47. A method for treating at least a selected region at depth of a patient's body while protecting tissue above the selected region, comprising:
- (a) selectively delivering radiation to the patient's body above said selected region to heat the region;
 - (b) concurrently cooling patient tissue above said selected region to a
 - 30 temperature below that of the selected region; and
 - (c) applying at least one of mechanical, acoustic and electrical stimulation to said region.

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48. A method for treating at least a selected region at depth of a patient's body while protecting tissue above the selected region, comprising:

- 5 (a) selectively delivering radiation to the patient's body above said selected region to heat the region, said radiation being selected so as not to be scattered or absorbed by tissue above said selected region sufficiently to prevent sufficient radiation from reaching the selected region to effect a desired treatment; and
- (b) concurrently cooling patient tissue above said selected region to a temperature below that of the selected region.

10 49. A method as claimed in claim 48 wherein said selected region contains subdermal fat; and wherein said radiation at least includes at least one wavelength selectively absorbed by fat.

15 50. A method for hair management comprising:

- (a) selectively delivering radiation to the patient's body above a region of subdermal fat containing a bulb for a hair to be removed to heat the region and thus the hair bulb, resulting in damage thereto; and
- 20 (b) concurrently cooling patient tissue above said region to a temperature below that of the region.

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FIG. 1

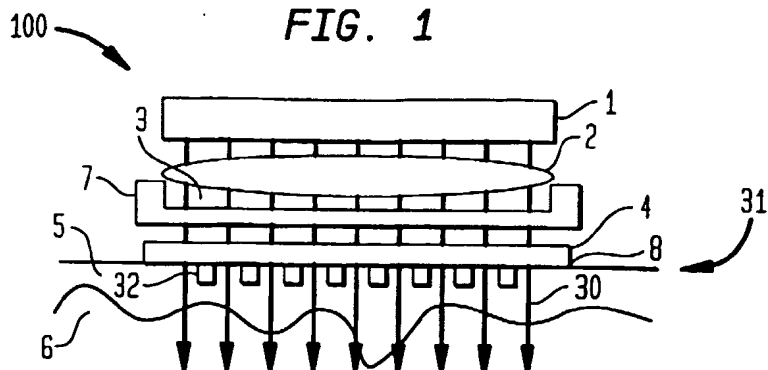


FIG. 2

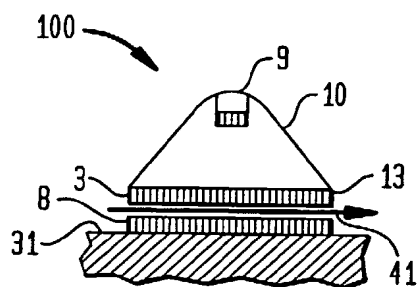
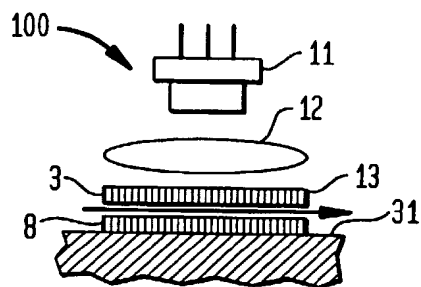


FIG. 3



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FIG. 4

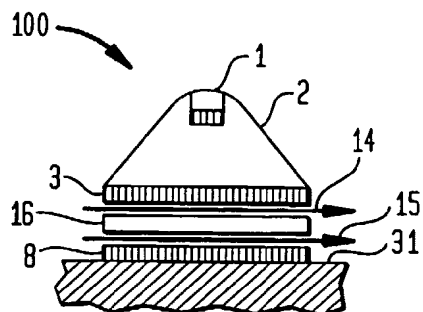


FIG. 5

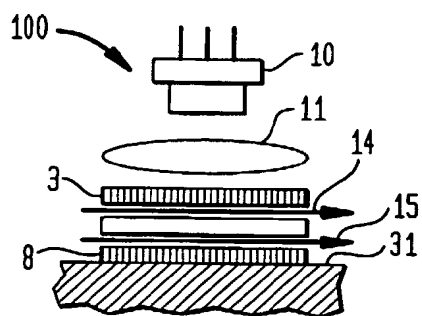
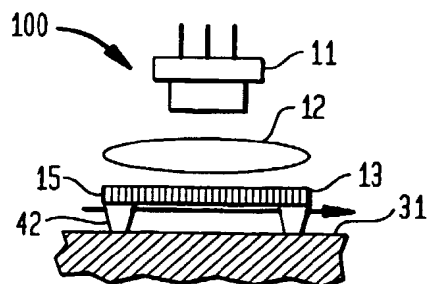


FIG. 6



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FIG. 7

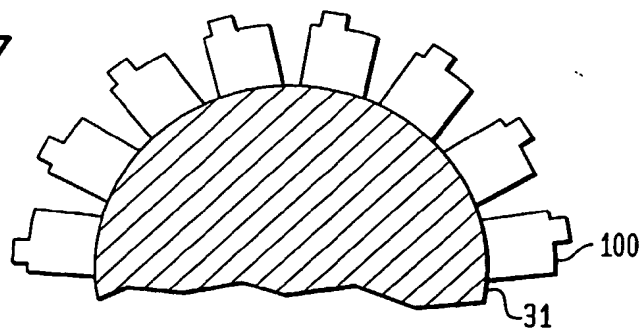


FIG. 8

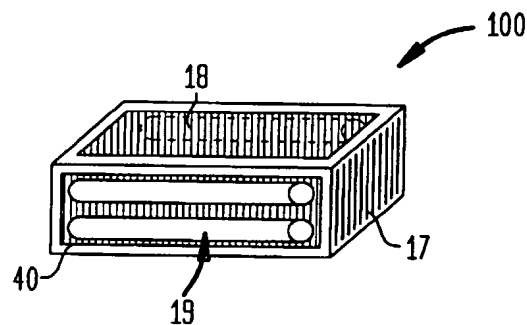


FIG. 9

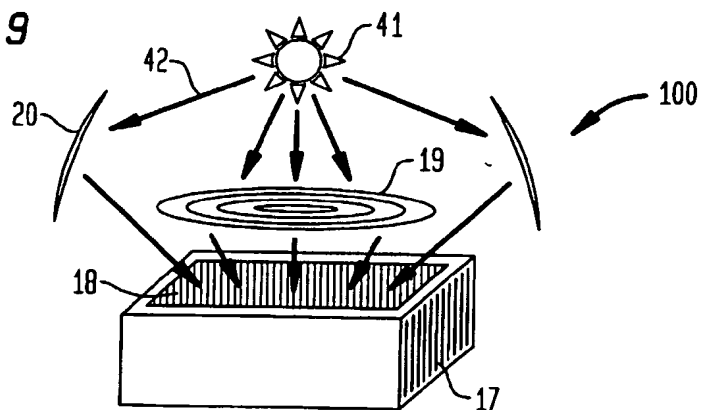


FIG. 10

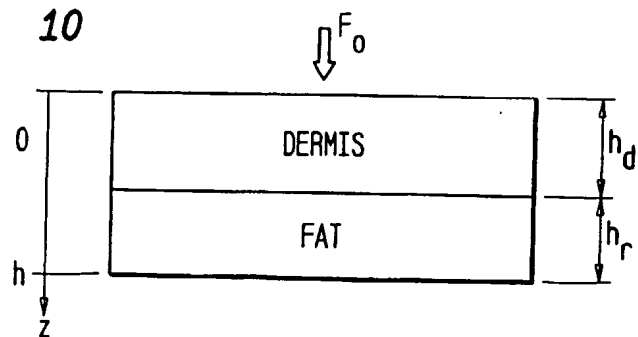


FIG. 11

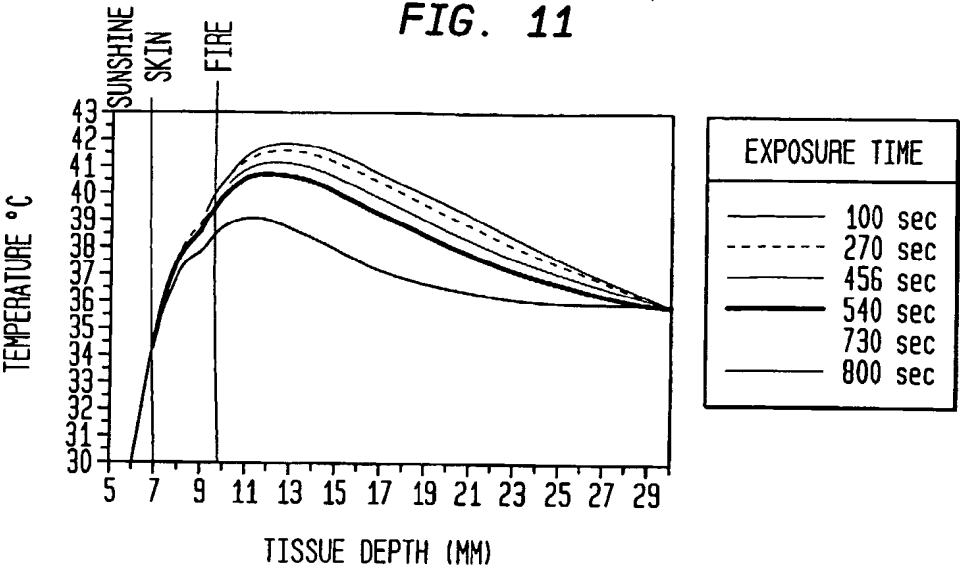
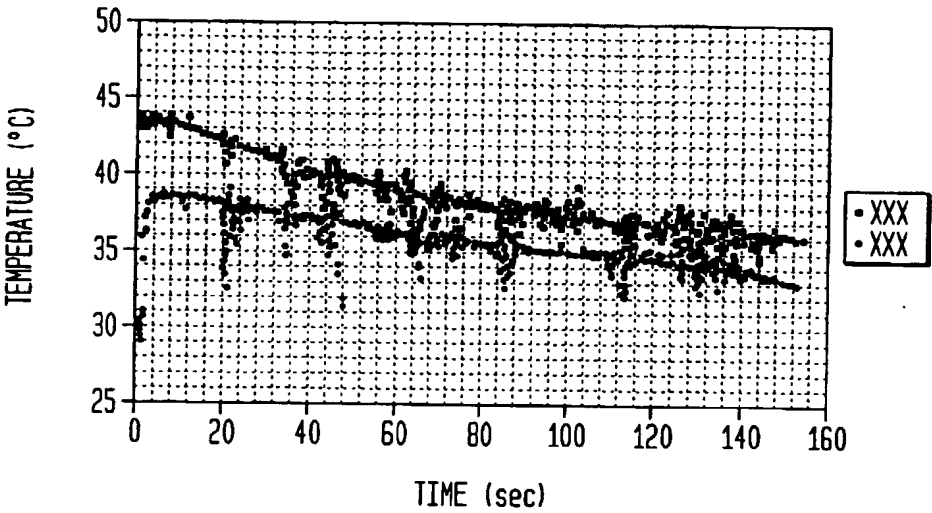
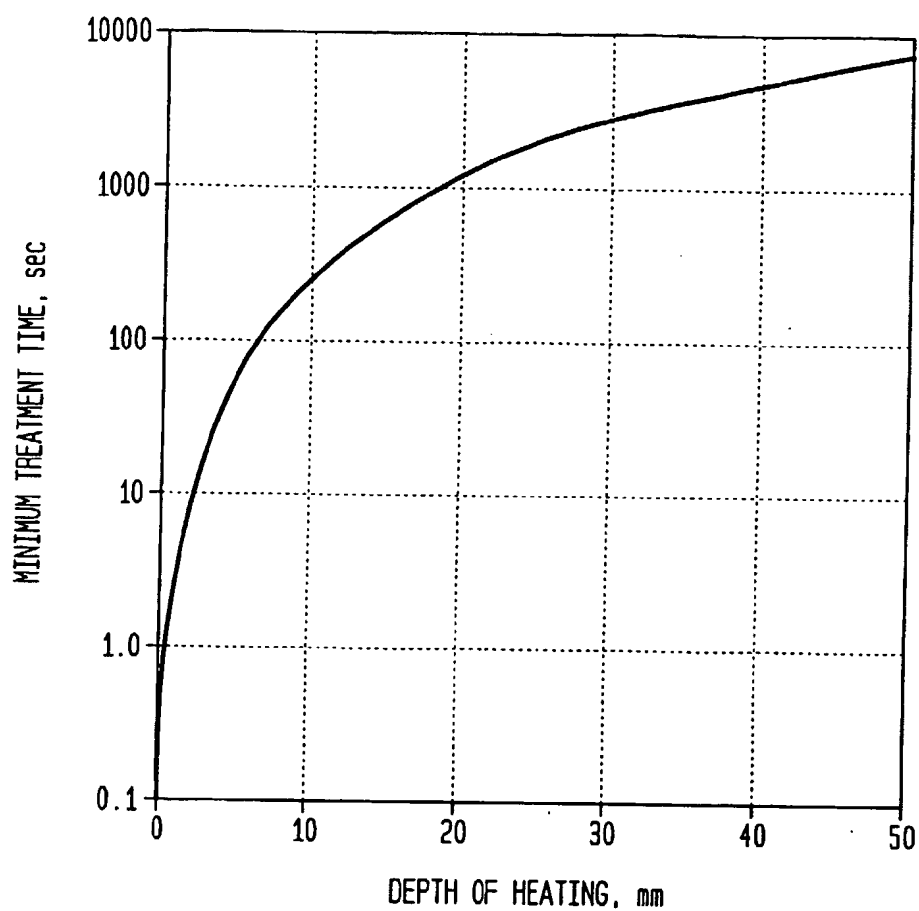


FIG. 12



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FIG. 13



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/19474

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B18/18 A61B18/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001/041886 A1 (DURKIN ANTHONY J ET AL) 15 November 2001 (2001-11-15) paragraph '0010! - paragraph '0014! paragraph '0039! - paragraph '0058!	1-4, 9-21, 24
Y	----	5-8, 22, 23
Y	FR 2 199 453 A (BUSSE FRANCIS) 12 April 1974 (1974-04-12) page 2, line 31 - page 3, line 27 page 4, line 5 - line 40	5-8, 22, 23
A	EP 0 724 894 A (ESC MEDICAL SYSTEMS LTD) 7 August 1996 (1996-08-07) page 4, line 17 - line 41 ----- -/--	4

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"8" document member of the same patent family

Date of the actual completion of the international search

15 September 2003

Date of mailing of the international search report

22/09/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Beck, E

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/19474

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	AU 18515 83 A (BLAKE A J; JACKA F J; UNIV ADELAIDE) 1 March 1984 (1984-03-01) page 3, line 17 -page 4, line 21 ----	5
A	WO 99 49937 A (GEN HOSPITAL CORP ; PALOMAR MEDICAL TECHNOLOGIES I (US)) 7 October 1999 (1999-10-07) page 13, line 1 - line 12 page 14, line 21 -page 15, line 3 page 17, line 11 - line 20 -----	13-18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/19474

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 25-50
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for therapeutic treatment of the human or animal body, some of them even with surgical character.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/19474

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		WO 9949937 A1	07-10-1999
		US 6605080 B1	12-08-2003

(19) World Intellectual Property
Organization
International Bureau



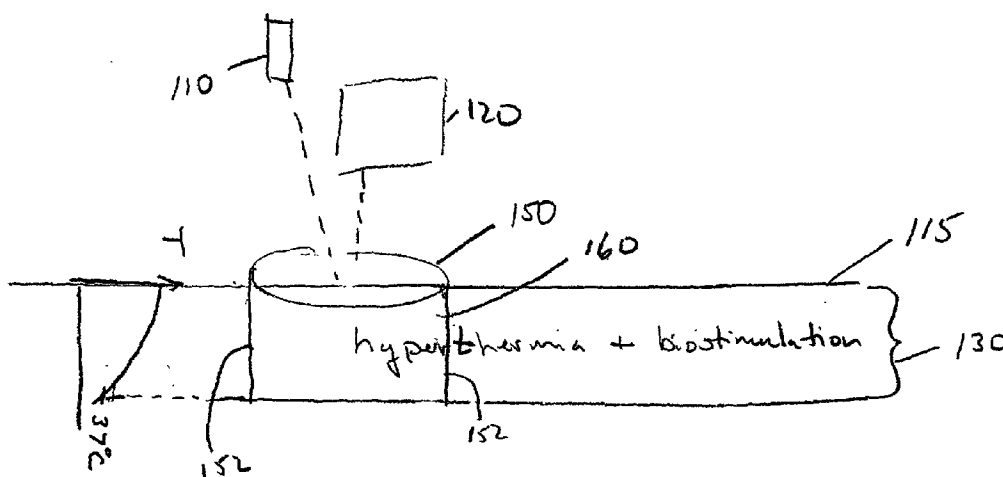
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22 April 2004 (22.04.2004)

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(10) International Publication Number
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- (71) Applicant: **PALOMAR MEDICAL TECHNOLOGIES, INC.** [US/US]; 82 Cambridge Street, Burlington, MA 01803 (US).
- (72) Inventors: **ALTSHULER, Gregory, B.**; 137 Marion Street, Wilmington, MA 01887 (US). **YAROSLAVSKY, Ilya**; 9214 Avalon Drive, Wilmington, MA 01887 (US). **PANKRATOV, Michail**; 16 Appleton Street, Waltham, MA 02453-5402 (US). **GAL, Dov**; 40 Kenwood Street #2, Brookline, MA 02446 (US).
- (74) Agents: **ENGELLENER, Thomas J.** et al.; Nutter McClennen & Fish LLP, World Trade Center West, 155 Seaport Boulevard, Boston, MA 02210-2604 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: APPARATUS FOR PERFORMING PHOTOBIOSTIMULATION



(57) Abstract: The present invention provides devices for modulating the efficacy and/or increasing the efficiency of treatment of disease and/or cosmetic conditions through photobiostimulation combined with heating and/or cooling of the treatment region. In one aspect, devices of the present invention are directed to modulating the efficacy of photobiostimulation in a target region by controlling the temperature in the region and/or its surrounding volume. According to some aspects of the present invention, tissue is heated such that biostimulation is applied to tissue that is hyperthermic. Alternatively, portions of the target region can be cooled to selectively target biostimulation to a specific region at a desired depth below the skin surface. A feedback mechanism is also provided so that the temperature of the target region can be selectively and accurately controlled.

WO 2004/033040 A1

- 1 -

APPARATUS FOR PERFORMING PHOTOBIOSTIMULATION

PRIORITY

5 The present invention claims priority to U.S. Provisional Application No. 60/416,664, filed October 7, 2002 entitled "Methods and Apparatus for Performing Photobiostimulation."

BACKGROUND OF THE INVENTION

10 This invention is directed to methods and apparatus for performing photobiostimulation of tissue, and more particularly to methods and apparatus for performing temperature controlled photobiostimulation of tissue.

 Low-power emitting lasers (i.e., typically less than 100 mW) have been used worldwide over the past three decades to treat a variety of clinical conditions. For
15 example, light has been reported to stimulate DNA synthesis, activate enzyme-substrate complexes, transform prostaglandins and produce microcirculatory effects. There have been numerous reports of such effects resulting from irradiating endogenous chromophores (i.e., without application of exogenous photosensitizers) in cells or tissues.

20 The use of low-level light to achieve such photochemical responses is commonly referred to as photobiostimulation. In addition to laser light, photobiostimulation may be achieved using other monochromatic or quasi-monochromatic light sources (e.g., LEDs) or by suitably filtering broadband light sources (e.g., filtering fluorescent lamps, halogen lamps, incandescent lamps, discharge lamps, or natural sunlight).

25 Biostimulation achieved by laser sources is also referred to as low-level laser therapy (LLLT).

 Low-level light or low-level laser therapy stimulates the tissues and promotes healing by penetrating deep into the tissues initializing the process of photobiostimulation. The light energy is absorbed in cytochromes and porphyrins
30 within cell mitochondria and cell membranes producing a small amount of singlet oxygen. Healing results from such treatments as demonstrated in many thousands of clinical study cases. Typically, patients can expect to feel noticeable improvement after four to six sessions for acute conditions and after six to eight treatments for chronic

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conditions. In many instances, photobiostimulation can be a viable alternative to surgery.

The photochemical process resulting from photobiostimulation is believed to involve the integration of photons into the cellular machinery of biochemical reactions. Generally, the principle of light absorption and integration of the photon energy into the cellular respiratory cycle is a well-known natural phenomenon. Photosynthesis and vision are two examples of this phenomenon. In these processes, the photoacceptor molecules are chlorophyll and rodopsin, respectively.

In the case of photobiostimulation, several concurrent mechanisms of action have been demonstrated in vitro. One example of such a mechanism involves cytochrome c oxidase, which is a primary cellular photoacceptors of low level light. Cytochrome c oxidase is a respiratory chain enzyme residing within the cellular mitochondria, and is the terminal enzyme in the respiratory chain of eukaryotic cells. In particular, cytochrome c oxidase mediates the transfer of electrons from cytochrome c to molecular oxygen. The involvement of cytochrome c is known to be central to the redox chemistry leading to generation of free energy that is then converted into an electrochemical potential across the inner membrane of the mitochondrion, and ultimately drives the production of adenosine triphosphate (ATP). Accordingly, it has been postulated that photobiostimulation has the potential of increasing the energy available for metabolic activity of cells.

It has been further demonstrated that photobiostimulation may be used to enhance cellular proliferation to achieve therapeutic effects. ATP molecules serve as a substrate to cyclic AMP (cAMP) which, in conjunction with calcium ions (Ca^{2+}), stimulate the synthesis of DNA and RNA. cAMP is a pivotal secondary messenger affecting a multitude of physiological processes such as signal transduction, gene expression, blood coagulation and muscle contraction. Accordingly, it has been postulated that an increase in ATP production by photobiostimulation may provide a means to increase cell proliferation and protein production.

Light-stimulated ATP synthesis, such as that caused by photobiostimulation, is wavelength dependent. Karu (*Lasers in Medicine and Dentistry*. Ed. Z. Simunovic, Vitgraf:Rijeka, 2000, pp.97-125.) demonstrated in vitro that prokaryotic and eukaryotic cells are sensitive to two spectral ranges, one at 350-450 nm and another at 600-830 nm.

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Karu demonstrated that the light receptors of the red wavelengths are the semichinon type of the flavoproteins of the reductase (dehydrogenases) and the cytochrome a/a3 of cytochrome c. Cytochrome c oxidase in its oxidation form is the specific chromophore of 800 nm through 830 nm wavelength range.

Another mechanism of biostimulation involves causing a very limited irritation to the blood cells and walls in the vessels of the dermis. This results in a low-grade inflammatory/growth response. Inflammatory mediators are released through the vessel walls that stimulate fibroblast activity and eventually lead to a "healing" effect.

While the above mechanisms and positive effects have been demonstrated in numerous in vitro studies, results of clinical trials have been so far inconclusive. While some groups reported varying degree of success in the treatment of a range of conditions, others observed no or minimal effect. U.S. Patent Nos. 5,514,168, 5,640,978, 5,989,245, 6,156,028, 6,214,035, 6,267,780, and 6,221,095, which are hereby incorporated by reference, provide examples of methods and devices for biostimulation. While various methods and devices of biostimulation exist in the art, more efficient and efficacious methods of treatment that yield quicker results with less treatment sessions are needed.

Photobiostimulation has been typically performed using relatively inexpensive sources, such as diode lasers or LEDs such as Ga-As and Ga-Al-As (e.g., emitting in the infrared spectrum (600- 980 nm)). Existing sources of low power laser light and light emitting diodes (LEDs) deliver power levels ranging from 1 to 100 milliwatts; accordingly power densities necessary to perform photobiostimulative procedures are achieved by concentrating the light beam output into a very small spot sizes (typically less than 10 mm). This results in a typical power density at the skin surface in a range between 1 and 100 mW/cm². The small beam size makes a scanning device necessary to treat large areas. Treatment times used in most studies are in the range of 5 to 30 min and multiple treatments are often required.

There exists a need in the art for improved methods and devices for biostimulation that improve efficacy of treatment of disease and/or cosmetic conditions and, thus, will require less treatment sessions.

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BRIEF SUMMARY OF THE INVENTION

The present invention provides methods and devices for modulating the efficacy and/or increasing the efficiency of treatment of disease and/or cosmetic conditions through photobiostimulation combined with heating and/or cooling of the treatment region. In one aspect, methods and devices of the present invention are directed to modulating the efficacy of photobiostimulation in a target region by controlling the temperature in the region and/or its surrounding volume. According to some aspects of the present invention, tissue is heated such that biostimulation is applied to tissue that is hyperthermic. Alternatively, portions of the target region can be cooled to selectively target biostimulation to a specific region at a desired depth below the skin surface. A feedback mechanism is also provided so that the temperature of the target region can be selectively and accurately controlled.

The present invention is based in part on the discovery that heat enhances the effects of biostimulation. Heat enhanced biostimulation can take various forms. For example, heat may slow the repair of radiation-induced DNA damage, leaving more damage unrepaired and increased amounts of free radicals in the target region resulting in increased effects of biostimulation. Heat may also induce the production or activation of heat shock proteins or modify the rates of enzymatic processes. Currently, treatment sources and operating conditions used in conventional photobiostimulation provide negligible heating of treated tissue (e.g., less than 1°C above normal body temperature).

In one aspect, the invention provides methods and devices for biostimulating a target region of a subject comprising irradiating a target region with a radiation, generated by a radiation source which has at least one selected wavelength component suitable for biostimulation, for a selected time duration and controlling a temperature of the irradiated target region with a source independent of said biostimulating radiation so as to modulate efficacy of said biostimulation. The time duration is chosen so as to cause biostimulation of the target region. In some embodiments, the target region is disposed at a depth below a skin surface of the subject. Time duration can be selected based on the desired application. Preferably time durations are chosen to be in a range of about 10 seconds to about one hour or in the range of about 10 minutes to about one hour. The temperature can be controlled, for example, by placing the target region in thermal contact with a surface having a selected temperature, by generating a flow of a

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fluid or air over the target region to be in thermal contact therewith, by applying electromagnetic or ultrasound radiation to the target region, or by applying a vaporizing cream, or a precooled and/or preheated cream or lotion to the target region. Those
5 having ordinary skill in the art will appreciate that the other methods may also be utilized for controlling the temperature of the target region and/or its surrounding volume.

The wavelength component can be selected to be in a range of about 380 nm to about 1250 nm, in a range of about 380 nm to about 600 nm, in a range of about 380 nm
10 to about 450 nm, in range of about 600 nm to about 700 nm, or in a range of about 760 nm to 880 nm depending on the desired application. The radiation source can preferably generate radiation with a narrow bandwidth, for example, a bandwidth less than about 100 nm.

The radiation can deliver a power flux in a range of about 1 to about 250
15 mW/cm² to the target region, or more preferably in a range of about 10 to about 100 mW/cm². The radiation can deliver an energy flux in a range of about 1 Joule/cm² to about 1000 Joules/cm², or more preferably in the range of about 1 Joule/cm² to about 100 Joules/cm², to the irradiated target region during irradiation time.

According to some aspects of the invention, the target region is irradiated by
20 exposing it to a beam of radiation having a cross-sectional area in a range of about 1 cm² to about 10 cm². However, the beam's cross-section can be increased based on the application.

In some aspects, the step of controlling temperature includes heating the irradiated target region, referred to as hyperthermia herein, so as to increase efficacy of
25 the biostimulation. The heating step can be performed by contact heating, convection, or application of electromagnetic radiation, such as ultrasound, microwave, or infrared energy. Hyperthermia is defined herein to be a temperature greater than normal body temperature. Normal body temperature can range from 36.1°C to 37.2°C depending on the time of day. Accordingly, the temperature of the surface area of the target region to
30 which biostimulation is applied in practice of the invention can be increased to 37-50°C and preferably 37-45°C. In some embodiments, the temperature of the target area can be increased to be within a range of about 37-42°C or, alternatively, be within a range of about 38-42°C. In other embodiments, the temperature of the target area is increased to

be within a range of about 38-41°C. The temperature is preferably elevated above normal body temperature, but below a temperature at which pain and denaturation of a significant concentration of critical biomolecules occurs.

5 Further aspects of the present invention are directed to cooling a target region to which biostimulative radiation is applied. According to at least some aspects of the invention, a portion of the region of tissue is cooled such that the skin is protected from heat damage and/or the efficacy of biostimulation in the region is reduced to control depth of treatment. The target region can be cooled to a value in a range of about 0°C to
10 about 36°C, or about 10-36 °C, or about 15-36 °C, or about 20-36°C, or about 28-36°C.

In some embodiments, controlling the temperature comprises utilizing a separate radiation source to heat the target region irradiated with biostimulating radiation. The separate radiation source can include a narrowband source or broadband source. The separate radiation source can generate radiation having one or more wavelength
15 components in a range of about 380 nm to about 2700 nm, preferably in a range of about 1000 nm to about 1250 nm, or more preferably in a range of about 700 nm to about 900 nm.

In one aspect of the invention, the step of controlling the temperature of the irradiated target region comprises heating a first selected portion of the target region and
20 cooling a second selected portion of the target region. Heating and cooling can be either simultaneous or sequential. Beneficial effects may result from rapidly changing or fluctuating the temperature of the target region before, during, or between irradiation sessions.

In another aspect of the invention, a method of biostimulating a target region of a patient disposed at a depth below the patient's skin is disclosed. The method includes
25 exposing a portion of the patient's skin for a selected time duration to a radiation having at least one selected wavelength component capable of penetrating to a depth associated with the target region so as to irradiate the target region. The temperature of a volume of the patient through at least a portion of which the radiation traverses to reach the
30 target region is controlled so as to modulate biostimulation within that volume relative to the target region. The wavelength component and the time duration are chosen to cause biostimulation within the target region. The temperature can be controlled to cool the volume and decrease biostimulation therein. For example, the temperature of the

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volume can be decreased to be within the range of about 0°C to about 36°C or preferably in a range of about 15°C to about 36°C. The wavelength component can be selected to be in a range of about 380 nm to about 1250 nm or more specific ranges described
5 herein. The radiation source can generate radiation with a narrow bandwidth that can be less than about 100 nm.

In yet another aspect, the invention discloses a device for biostimulating a patient's target region that includes a first source for generating electromagnetic radiation having one or more wavelength components suitable for causing
10 biostimulation in the target region; a radiation guidance device optically coupled to the source for delivering the radiation to the target region; and a second source in communication with the target region for controlling a temperature of the target region in order to modulate efficacy of biostimulation caused by the electromagnetic radiation. The first source can generate radiation having a narrow bandwidth, for example, less
15 than about 100 nm. The first source can generate radiation having one or more wavelength components in a range of about 380 nm to about 1250 nm. The second source can include a source of electromagnetic radiation generating radiation suitable for heating the target region so as to enhance the efficacy of biostimulation. For example, the second source can generate one or more wavelength components in a range of about
20 380 nm to about 2700 nm.

In a related aspect, the device can further include an optical fiber coupled at an input thereof to the first radiation source and an output thereof to the radiation guidance device, for example, a lens system, so as to direct light generated by the radiation source to the lens system. The lens system can have at least one movable lens to allow
25 adjusting a cross-sectional area of a radiation beam generated by the first source for irradiating the target region. The lens system can comprise a Fresnel lens.

In another aspect, the radiation guidance device may include a beam splitter adapted to receive a radiation beam from the first source in order to generate a plurality of beam portions, and one or more reflective surfaces optically coupled to the beam
30 splitter to direct one or more of the beam portions to a surface of the patient's skin so as to irradiate the target region. The reflective surfaces can allow a substantially uniform illumination of the skin surface. The beam splitter can be, for example, a prism, and at least one of the reflective surfaces can exhibit a curved profile.

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In another aspect, the invention provides a method of biostimulating a subject's target region that includes irradiating the target region with radiation having one or more wavelength components suitable for causing biostimulation within the target region, and
5 actively controlling a temperature of at least a portion of the target region to ensure it remains within a pre-defined range of an operating temperature in order to modulate efficacy of biostimulation within the target region. The step of actively controlling the temperature can include measuring a temperature of a portion of the patient's skin in thermal contact with the target region and comparing the measured temperature with at
10 least one pre-defined threshold. The amount of heat delivered to or extracted from the target region can be controlled in response to the comparison of the measured temperature with the pre-defined threshold.

In yet another aspect, the invention provides a method for biostimulating a plurality of target regions of a subject by moving a radiation source over a portion of the
15 subject's skin so as to irradiate sequentially a plurality of target regions with radiation having at least one wavelength component suitable for causing biostimulation. The moving of radiation source can be performed at a rate selected to expose each of the regions to sufficient radiation for causing biostimulation therein. The temperature of the target regions can be controlled by a source independent of the biostimulating radiation
20 so as to modulate efficacy of biostimulation within each of the target regions. The moving radiation source can expose each target region, once, or alternatively, multiple times, to biostimulative radiation.

BRIEF DESCRIPTION OF THE DRAWINGS

25 Figure 1 schematically illustrates an embodiment of the invention in which a target region, which extends from the surface of the skin to a selected depth, is heated such that biostimulation is applied to a hyperthermic volume of tissue;

Figure 2 schematically illustrates another embodiment of the invention in which
30 biostimulation is applied to a heated target region in proximity of the skin surface while biostimulation is applied simultaneously to an unheated volume below the target region;

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Figure 3 schematically illustrates another embodiment of the invention in which photobiostimulation is generated in a volume of tissue at a depth region below the surface of skin while cooling is applied to the surface of skin;

5

Figure 4 schematically illustrates another embodiment of the invention in which biostimulation is applied to a hyperthermic volume of tissue that is at a selected depth below the surface of the skin, and unheated volumes are located above and below the hyperthermic volume of tissue;

10

Figure 5 schematically illustrates another embodiment of the invention in which enhanced biostimulation occurs in a first volume of tissue, which is both hyperthermic and located at a selected depth below the surface of the skin, and biostimulation (without hyperthermia) also occurs in a second volume of tissue that is located below the first volume of tissue;

15

Figures 6 is a graph of selected temperature profiles of type II skin using exemplary wavelengths of monochromatic light without skin cooling;

20

Figures 7 is a graph of selected temperature profiles of type II skin using exemplary wavelengths of monochromatic light with parallel skin cooling;

Figure 8 is a schematic diagram of a light projection system for biostimulating a target region, according to the teachings of the invention;

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Figure 9A is an exemplary embodiment of a light projection system for forming substantially uniform illumination of a non-flat surface;

Figure 9B is a schematic diagram of an exemplary beam splitter suitable for use in a device according to the teachings of the invention;

30

Figure 10 is a schematic diagram of another exemplary embodiment of a light projection system for forming substantially uniform illumination over a non-flat surface;

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Figures 11A is a schematic diagram of another embodiment of a light projection system according to the teachings of the invention that utilizes a rotatable head to provide substantially uniform illumination to a non-flat surface, where the rotatable head is positioned to direct light onto a front portion of the non-flat surface

Figures 11B is a schematic diagram of another embodiment of a light projection system according to the teachings of the invention that utilizes a rotatable head to provide substantially uniform illumination to a non-flat surface, where the rotatable head is positioned such that light is directed onto a first side portion of non-flat surface;

Figures 11C is a schematic diagram of another embodiment of a light projection system according to the teachings of the invention that utilizes a rotatable head to provide substantially uniform illumination to a non-flat surface, where the rotatable head is positioned such that light is directed onto a second side portion of non-flat surface;

Figure 12A is a graph of the temperature of type II skin surface as a function of time of exposure to a 800 nm radiation at a flux of 680 mW/cm^2 , wherein the beam has a diameter larger than 2.5 cm;

Figure 12B is a graph of temperature profiles in which the type II skin surface is cooled and kept at 36°C while being exposed to different wavelengths of radiation according the invention;

Figure 13A is an exemplary embodiment of a light projection system for use in the invention;

Figure 13B depicts an exemplary set of lens parameters according to the invention;

Figure 14 illustrates an exemplary embodiment of a device, according to the invention, capable of irradiating a target region and controlling the temperature of that region through a feedback mechanism; and

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Figure 15 illustrates an exemplary embodiment of a device, according to the invention, capable of irradiating a target region using a 2D matrix of radiation sources.

5

DESCRIPTION OF THE INVENTION

In one aspect, the present invention is directed to controlling the efficacy of photobiostimulation in a target region by controlling the temperature of that region. The heating or cooling of the target region, i.e., patient's skin, hair, eye, teeth, nails, or other body tissue, can trigger biological processes within the body that can work synergistically with photobiostimulation to yield better, more efficient results. The temperature of the target region is modulated during, prior to, or between photobiostimulation. The synergy between irradiation and temperature modulation can vary depending on the order of application and/or the disease or cosmetic condition to be treated. In a preferred embodiment, modulation of the temperature and irradiation occurs simultaneously.

In one embodiment, the temperature of the target region is increased. Heating of tissue, hyperthermia, leads to increased local tissue perfusion and increased blood and lymph circulation. The increase in blood flow has multiple effects on photobiostimulated tissues. The cellular biochemical reactions of biostimulation are accelerated since the rates of some enzymatic reactions increase at higher temperatures. Additionally, more oxygen is available for the increased cellular metabolism, and the toxic by-products of metabolism are removed more readily, through the blood and lymphatic circulation. In addition, heating of blood vessels can increase vessel wall and/or cell wall permeability, which may result in improved delivery of therapeutic additives (i.e., vitamins, antioxidants, lotions, etc.) or drugs to the target area. For example, topical drugs may be enclosed in thermosensitive liposomes that selectively release their drug content when exposed to heat.

Hyperthermia in a tissue to be treated may be achieved by use of any suitable technique, including but not limited to use of contact heating, convection (i.e., by heated air), or application of electromagnetic radiation. In some embodiments, hyperthermia in a tissue to be treated is achieved by absorption of a portion of the incident electromagnetic radiation from a biostimulative source used to biostimulate the tissue. For example, absorption of electromagnetic radiation may be by tissue chromophores

such as melanin, hemoglobin, water, lipids or other chromophores which cause a photothermal interaction leading to an increase in tissue temperature. Hyperthermia generates a cascade of events, such as increasing vasodilation, increasing blood
5 circulation, increasing production of heat shock proteins, which can act synergistically with photobiostimulation resulting in improved efficacy of treatment.

Additionally, local hyperthermia is known to activate the heat shock (HS) response, *thermotolerance* and *hormesis* (P. Verbeke, et al. *Cell Biol Inter.* 2001; 25:845-857). The phenomenon of *thermotolerance* is defined as the capacity of cells,
10 following a cycle of heat stress and recovery, to survive a second stress, which would otherwise be lethal. Mild heat shock treatment may prevent cell death from a variety of subsequent stresses. Similar to exposure of cells and organisms to stresses such as caloric restriction, exercise, oxidative and osmotic stress, heavy metals, proteasome inhibitors, amino acid analogues, ethanol, and metabolic poisons, heat shock treatment
15 induces a cellular stress response leading to the preferential transcription and translation of heat shock proteins (HSPs). Numerous families of HSPs have been identified (P. Verbeke, et al. *Cell Biol Inter.* 2001; 25:845-857).

When a cell encounters a stressor, modifications of the cytoskeleton, cytoplasmic structures, cell surface morphology, cellular redox status, DNA synthesis, changes in
20 protein metabolism and protein stability occur. Such stress generates a molecular remodeling or damage, especially abnormal folded proteins, which can aggregate and initiate a sequence of stress responses. The induction of the HS response occurs through molecular links between the environmental stresses and the stress response. When stress alters protein folding, or proteins begin to unfold and denature, HSPs have been shown
25 to assist in protein refolding, to protect cellular systems against protein damage, to solubilize aggregates to some extent, to sequester overloaded and damaged proteins into large aggregates, to target fatally damaged proteins for degradation, and to interfere with the apoptotic progression (P. Verbeke, et al. *Cell Biol Inter.* 2001; 25:845-857).

HSPs that are involved in the renaturation of unfolded proteins are referred to as
30 chaperones. Chaperones recognize and bind to other proteins when they are in non-native conformations and are exposing hydrophobic sequences. Such HSPs protect many different systems involved in maintenance of cellular functions. Some HSPs induce an increase in the cellular glutathione (GSH) level leading to the protection of the

mitochondrial membrane potential during stress. Members of the HSP70 and HSP90 families are associated with the centrosome. They are known to bind and stabilize actin, tubulin and the microtubules/microfilament network, playing a role in the cellular morphology and transduction pathways.

Thermotolerance is believed to be mainly due to the orchestrated regulation of expression and accumulation of various HSPs in the endoplasmic reticulum and in the cytosol, leading to macromolecular repair mechanisms as a defensive strategy against subsequent challenges. A further characteristic of responses to HS is that various HSPs are soluble and transfer across the cell membrane to other adjacent cells. Consequently, the protective stress response is transferable to neighboring cells that might not be able to mount such a reaction. Accordingly, a next treatment can be done with higher temperature. This mechanism can be used to increase the maximum tolerable incident power applied to the skin surface. Specifically, the power can be increased gradually, allowing the organism to adapt to the thermal stress and thus survive a higher level of hyperthermia than would be possible without such adaptation.

In addition to the HSP-dependent effects described above, HSP-independent effects may arise from hyperthermia. Other mechanisms of stress tolerance include the synthesis of osmotic stress protectants, modifications of the saturation of cell membrane lipids, and expression of enzymes such as radical scavengers.

Similar to thermotolerance, *hormesis* is a response to repeated mild stress, which enhances cellular defense processes. *Hormesis* is a process by which cells adapt to gradual changes in their environment so as to be able to survive subsequent exposure to otherwise lethal conditions. Such a phenomenon has been observed in relation to irradiation, toxins, heat shock and other stresses. Ratan et al observed anti-aging *hormetic* effects of repeated mild HS on human fibroblasts (Rattan et al. *Biochem Mol Biol Int* 1998;45:753-759). Kevelaitis et al showed that local and brief application of heat (42.5 °C for 15 minutes) to the myocardium improved cardiac systolic and diastolic functions (Kevelaitis et al. *Ann Thorac Surg* 2001;72:107-113).

The above indicates that systems according to aspects of the present invention should improve the clinical utility and outcome of biostimulation therapy. It further appears that aspects of the present invention provide synergistic effects of photochemical biostimulation of cells and mild tissue hyperthermia, which stimulate

HSP-dependent and HSP-independent thermotolerance, and/or hormesis. This synergism may lead to repair of cell damage and improved functionality of compromised cells. Those effects may help in the treatment of conditions associated with infection, acute and chronic inflammation, micro circulatory stagnation, and may also stimulate regeneration and rejuvenation of tissues subjected to degenerative processes, for example, by stimulating fibroblast proliferation, or by increases in growth factors eventually leading to new synthesis of intracellular and extracellular proteins, glycoproteins and lipid soluble molecules. Additional aspects of the present invention control the effectiveness of biostimulation provided by selectively delivered photobiostimulative light to deep structures through the use of temperature control (e.g., via heating and/or cooling of a tissue surface) and/or through control of radiation spot size.

In another aspect of the invention, a means for controlling specific mechanisms of photobiostimulation in order to achieve a desired therapeutic effect is provided. It is known that the biological response to photobiostimulation can vary as a function of the state of the biological system. For example, human fibroblasts can display a diversity of responses when exposed to outside stimuli (*Lasers in Medicine and Dentistry*. Ed. Z. Simunovic, Vitgraf:Rijeka, 2000, pp.97-125). In particular, both stimulation of proliferation of fibroblasts and an increase in production of type I collagen have been reported. However, production of collagen was affected in a manner inverse to the effect on cell proliferation, i.e., when proliferation increased, production of collagen decreased. Therefore, one can manipulate the state of the target system in order to channel the action of biostimulation into a desired pathway. One factor greatly influencing the state of the biological system is the temperature. The present invention provides a way to fine-tune the resulting biological response through the control of the temperature of the biostimulated area.

The present invention provides methods and devices for modulating the efficacy of biostimulation. The term "modulates efficacy" as used herein refers to a change of the resulting biostimulation effects of greater than 10%, preferably greater than 20%, more preferably greater than 30%, more preferably greater than 40%, more preferably greater than 50%, more preferably greater than 60%, more preferably greater than 70%, more preferably greater than 80%, more preferably greater than 90% and most

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preferably greater than 100%. The efficacy of biostimulation can be measured in terms of the time necessary to achieve a desired outward appearance, i.e., removal of wrinkles or scar tissue, or a time needed for patient satisfaction, i.e., pain relief, or the rate of the underlying enzymatic mechanisms. For example, substantially increasing the efficacy of biostimulation of a target region can refer to an increase in the rate of enzymatic processes in that target region of more than 10% relative to unstimulated steady-state condition. The rate of the enzymatic processes can be determined using any of the methods known in the art (See, for example, T. Bugg, *An Introduction to Enzyme and Coenzyme Chemistry*, Blackwell, 1997; Wright et al. *Photochem Photobiol.* 2002 Jul;76(1):35-46; Koekemoer et al. *Comp Biochem Physiol B Biochem Mol Biol.* 2001 Jul;129(4):797-807). For example, the enzymatic activity of cytochrome c oxidase or the rate of radical production, i.e., singlet oxygen, can be used as a measure of biostimulation in the target region. Free radical production can be determined by measuring superoxide dismutase (SOD) and catalase or glutathione peroxidase levels in the cytoplasm. In addition, indirect measures of free radical production can be used such as through consumption of antioxidants.

The mechanisms described above are illustrative, and are not exhaustive. Accordingly, they should not be considered as limiting the scope of the presented invention. Additionally, because photobiostimulation is an emerging field, the theories regarding the mechanisms achieving a given result are in many instance speculative.

Figures. 1-5 are schematic cross-sectional views of systems that illustrate five exemplary treatment scenarios for achieving photobiostimulation and temperature control (e.g., hyperthermia and/or hypothermia) of a volume of tissue according to at least some aspects of the present invention.

In each of the treatment scenarios, biostimulation is achieved by applying electromagnetic radiation to the skin surface from a source suitable for achieving biostimulation. For example, a suitable source may comprise a narrow bandwidth source, such as a monochromatic or quasi-monochromatic source. Appropriate sources can include lasers, LEDs or suitably filtered broadband sources (e.g., filtered lamps). The invention can also utilize a 2D matrix of radiation sources. A suitable narrow bandwidth source preferably has a bandwidth (i.e., wavelength range) of less than approximately 100 nm, preferably below approximately 20 nm and more preferably

below approximately 10 nm. The wavelength may be selected to achieve any known biostimulative effect. The wavelength of the radiation may be, for example, in a range of 380-2700 nm. For example, radiation with a wavelength in a range of about 380-600 nm
5 can be utilized for treating superficial tissues, while radiation with a wavelength in a range of about 600-1250 nm can be utilized for deep tissues. In an exemplary embodiment, preferred wavelength ranges that can be utilized for biostimulation are 380-450nm, 600-700nm, and 760-880nm. However, the choice of wavelength depends on the specific application. Biostimulation has uses in cosmetics, dentistry,
10 dermatology, ENT (ear, nose, and throat), gynecology, and surgery.

With reference to Figure 15, in one exemplary embodiment, a 2D matrix of radiation sources can be employed to irradiate a target region to cause biostimulation therein while simultaneously, or in separate time intervals, delivering heat thereto. The exemplary radiation matrix 1500 includes a plurality of radiation sources 1510 (depicted
15 as larger circles) that provide radiation with one or more wavelength components suitable for causing biostimulation in tissue, and a plurality of separate radiation sources 1520 (depicted as smaller circles) that can generate radiation with spectra suitable for heating a target region. A variety of radiation sources, such as LED or lasers, can be utilized for forming the 2D radiation matrix 1500.

20 Examples of applications of aspects of the invention include, but are not limited to, skin texture improvement, scar removal or healing, wrinkle removal, skin tightening, skin elasticity improvement, skin thickening, skin rejuvenation, cellulite treatment/fat reduction, vascular and lymph regeneration, subcutaneous collagen structure improvement, acne treatment, psoriasis treatment, fat reduction, hair growth stimulation,
25 treatment of alopecia, treatment of lentigo senile, treatment of striae, pain relief, wound healing, healing of epidermis and dermatitis, treatment of eczema, treatment of decubitus ulcer, healing of haematoma, treatment after skin resurfacing, odor reduction, muscles contraction relaxation, reduction of gum inflammation, reduction of pulpitis, treatment of herpes, treatment of alveolitis, aphtae and hyperemia, reduction of
30 oedema, drum healing, treatment of tinnitus, reduction of microscars and polyposis, treatment of adnexitis, bartholinitis, cervicitis, epiziotomy, HPV, menorrhagia, and parametritis, and vulvitis. Non-limiting wavelength ranges that can be used to treat a variety of diseases and cosmetic conditions can be found in Table 1.

Table 1. Examples of wavelength ranges useful for the treatment of specific diseases and cosmetic conditions.

<i>Dermatology/Cosmetology</i>	
Acne	390-450 and 600-700 nm
Scars	380-420, 620-680 and 760-830 nm (depending on scar nature)
Wrinkles	620-680 and 760-880 nm
Cellulite	760-880 nm
Striae	760-880 nm
Lentigo senile	600-700 nm
Alopecia	620-680 and 760-880 nm
Skin rejuvenation	600-700 and 760-880 nm
Hair growth stimulation	600-700 and 760-880 nm
Psoriasis	600-700 nm
<i>Dentistry</i>	
Gingivitis	380-450 and 600-700 nm
Gum inflammation	380-450 and 600-700 nm
<i>Other</i>	
Burns	760-880 nm
Pain relief	760-880 nm
Wound healing	380-1250 nm (depending on wound nature)

5 The treatment time is generally selected based on the time necessary to achieve hyperthermia of the tissue to be treated and the time necessary to irradiate the volume of hyperthermic skin with biostimulative radiation for a time sufficient to achieve a desired photobiochemical output.

10 According to some aspects of the invention, the time necessary to irradiate a volume of hyperthermic skin with biostimulative radiation can be determined using an assumption that there are approximately 10^{23} molecules/cm³ in human tissue, and that a minimum of one photon is to be delivered to each molecule during the course of a single

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photobiostimulative treatment. For example, for a 1 cm³ treatment volume, 10²³ photons must be delivered. Assuming uniform distribution of the absorbed photons and that light is delivered through a 1 cm² window, the light fluence at the skin surface is equal to 10²³ times the energy in one photon of the monochromatic light, and the fluence divided by the light power output of the source determines the typical minimum treatment time. Typical treatment times are 10 seconds to 60 minutes. In some embodiments, the pulse duration is between 1 min to 1 hour. In other embodiments, the pulse duration is between 10 min to 1 hour. Treatments can be performed as often as necessary. For example, treatment may occur 5 to 10 times, with 1 day interval between treatments. The typical amount of total energy delivered to the target area can range from 1 J/cm² to 1 KJ/cm² and preferably is between about 1 J/cm² to 100 J/cm².

According to the present invention, hyperthermia can be achieved by any known means of achieving hyperthermia at the depth indicated in each of the scenarios. In the case of photohyperthermia, the source may be a broadband radiation source or a narrowband radiation source, and may be pulsed or continuous wave (cw). In some embodiments, pulsed light may be synchronized to a biological period of a patient (e.g., the patient's heart pulse, biological cycle). Further details regarding photohyperthermia are discussed below.

Exemplary ranges for parameters (e.g., wavelengths fluxes, temperatures, areas) described herein below for achieving temperature control and biostimulation indicate values which may be used to achieve a specified treatment; the values to be utilized for a specific treatment will depend on many factors including, but not limited to, the patient's skin type, the part of the patient's body being treated, the desired treatment, the depth of the treatment, the temperature of the treatment volume, etc. Additionally, it is to be appreciated that parameters are also interrelated. For example, energy/fluence and time of application are inversely related, one increasing as the other decreases in order to provide a desired number of photons at a target volume. Examples of parameters which provide desired results are provided herein and parameters for other treatments can be determined by one of ordinary skill in the art from the information provided herein and/or empirically.

Figure 1 illustrates an exemplary embodiment of the invention in which a volume of tissue 160 is heated such that biostimulation is applied to a hyperthermic volume of tissue, wherein volume of tissue 160 extends from the surface of skin 115.

5 Volume of tissue 160 is defined by a depth region 130 and a skin surface area 150. While the side 152 of volume of tissue 160 is illustrated as perpendicular to the surface of skin 115, it is to be understood that the area of treatment in Figure 1, as well as those described below with reference to Figures 2-5, will typically increase with depth below the skin surface due to scattering of light by tissue. Additionally, while the boundaries of

10 the volume of tissue 160 are illustrated with continuous lines, it is to be understood that the actual volume of treatment may be highly irregular, and regions of tissue outside of such bounds may receive both biostimulation and hyperthermia; however, biostimulation and/or hyperthermia may be to a lesser degree than for tissue in volume of tissue 160.

15 Biostimulation may be achieved using radiation from a suitable photobiostimulative source 110 as described above. For example, source 110 delivers radiation to the skin surface 115 with a flux in the range of about 1-250 mW/cm², and preferably in the range of about 10-100mW/cm². Depth region 130 over which biostimulation is achieved is determined by the flux, the wavelength of light from source

20 110, and the size of area 150. For example, irradiation with radiation having a wavelength of 380-1250 nm at a flux 1-250 mW/cm² will achieve biostimulation to a depth up to 10 mm for a beam having a diameter of greater than 1cm. While area 150 is illustrated as circular, it is to be understood that area 150 (and the other skin surface areas described below with reference to Figures 2-5) may be oval, square, rectangular,

25 hexagonal or have any other suitable shape. Source 110 may be operated in contact with surface of skin 115 or project radiation onto surface of skin 115 from a distance.

Hyperthermia, an increased temperature, in volume of skin 160 may be achieved by any known source 120 capable of raising the temperature of volume 160 to a value within a range of about 37-50°C and preferably about 37-45°C. Normal body

30 temperature can range from 36.1°C to 37.2°C depending on the time of day. In some embodiments, the temperature of the target area can be increased to be within a range of about 37-42°C. In some embodiments, the temperature of the target area is increased to be within a range of about 38-42°C. In other embodiments, the temperature of the target

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region is increased to be within the range of about 38-41°C. In other embodiments, the temperature of the target region can be increased to about 38°C. In yet other embodiments, the temperature of the target region can be increased to about 39°C. In yet another embodiment, the temperature of the target region can be increased to about 40°C. For example, hyperthermia may be achieved by projecting hot air onto area 150, applying AC or DC electrical current, or using a conductive heat source (i.e., a device, such as a heated plate or heating pad, in contact with surface 115). Further examples of heating a tissue include using ultrasound and microwave radiation, as described in U.S. Pat. No. 5,230,334, and U.S. Pat. No. 4,776,086, respectively, herein incorporated by reference. If contact heating is desired, the heating source may be transparent to the biostimulative radiation such that the biostimulation can be provided to tissue through the heating source. Heating can be applied before, during or between photobiostimulation treatment sessions.

Optionally, source 120 may be a radiative source capable of achieving hyperthermia. Hyperthermia achieved using radiation is also referred to as photohyperthermia. A radiative source 120 may be any suitable radiative source that does not interfere with achieving biostimulation. To achieve hyperthermia, heating can be obtained using a broadband source or a narrowband source selected to achieve a desired temperature of tissue. Hyperthermia may be achieved using any suitable wavelength or wavelengths of electromagnetic radiation; for example, the radiation may be in the wavelength range 380-2700 nm; or preferably in the range 500-1250 nm, and more preferably in the ranges 650-900 nm and/or 1000-1250 nm. For example, the sources included in Figure 6 may be combined in a weighted manner to provide a suitable temperature profile. A radiative source 120 may be operated in contact with surface of skin 115 or project radiation onto surface of skin 115 from a distance.

It is believed that a radiative source 120 will not interfere with achieving biostimulation if the spectral density of the combined output of biostimulative source 110 and source 120 is predominated by wavelengths that effect biostimulation. For example, the spectral density of the wavelengths in the band that effects biostimulation is 100 times greater than the spectral density of light in any other band, and preferably greater than 1,000 times. The phrase "spectral density" is herein defined to refer to the

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number photons in a specified bandwidth (e.g., the bandwidth at which biostimulation is achieved).

5 Biostimulation according to aspects of the invention may be achieved using sources applied in a conventional small area of irradiation (e.g., a round area having a spot size less than 10 mm^2 in diameter), or a larger area (e.g., a round area having a spot size 1 cm^2 - 200 cm^2 or more up to and including the entire human body). Similarly, photohyperthermia according to aspects of the invention may be achieved using sources applied using a conventional small area (e.g., a round area having a spot size less than 10
10 mm in diameter), or a larger area (e.g., a round area having a spot size 1 cm^2 - 200 cm^2 or more). Large areas offer advantages, including but not limited to, reduced treatment time. For example, large areas may be used to treat large areas of tissue such as a face, neck, back or thigh. Methods of achieving a large area of irradiation are described in greater detail with reference to Figures 8-11 and 13 below.

15 The present invention recognizes that boundary effects diminish as the volume to be irradiated increases. As the volume of the target region increases, the probability that the scattered radiation will remain within the irradiated volume also increases. Therefore, radiation can penetrate the target tissue to a greater depth when a larger beam of irradiation and/or a larger target area is used. Accordingly, in some embodiments,
20 where treatment is to be affected to a significant depth in the tissue, a large area of illumination is used to effect the treatment. In contrast, conventional biostimulation apparatuses have used narrow incident beams, which are strongly attenuated such that the photons comprising the beam do not reach deeply into the dermis and subcutaneous tissue (and/or into muscles and bones) in high enough concentration to achieve the
25 desired biostimulation. Additionally, in a conventional biostimulation apparatus, since only small areas are treated at a given time, the beneficial effect arising from the treatment of large areas of tissue are nonexistent. In some embodiments, photobiostimulative radiation is directed onto the skin surface using an area of illumination greater than approximately 0.8 cm^2 (e.g., a circular spot size greater than 1
30 cm^2) and preferably greater than 1.6 cm^2 to provide biostimulation to tissue at relatively large depths below the skin surface, and to achieve time efficiencies resulting from treating a large area at one time. In one aspect, the present invention provides devices capable of providing such treatment.

Figure 2 illustrates another embodiment of the invention in which a volume of tissue 260 is heated such that biostimulation is applied to a hyperthermic volume of tissue 260, wherein volume of tissue 260 is adjacent to the surface of skin 115, and a volume of tissue 270 receiving biostimulation (without hyperthermia) is located below volume 260. Volume of tissue 260 is defined by a depth region 230 and an area 250. According to this aspect of the invention, the same light source 210 is used to produce both hyperthermia and biostimulation of volume of tissue 260. Light source 210 also produces biostimulation in volume 270 in a depth 240.

An additional advantage of embodiments according to this aspect of the invention is that the depth of the biostimulation zone is effectively increased by increasing the flux of source 210 relative to the flux provided in Figure 1. For example, an increase of flux incident on skin surface 115 from 100 mW/cm^2 to 200 mW/cm^2 is sufficient to induce pronounced hyperthermia, and will also increase effective biostimulation depth by up to 30% (i.e., an increase of the total biostimulation depth including depth regions 230 and 240 when compared to depth region 130 in Figure 1).

Hyperthermia and biostimulation are achieved in volume of tissue 260 by directing electromagnetic radiation from a narrowband source 210 onto an area 250. The wavelength of source 210 is selected to achieve a desired photobiostimulative result, and flux of source 210 is chosen to achieve a selected temperature profile as indicated by Figures 6 and 7. Biostimulation in volume 270 (defined by depth region 240 and area 250) is achieved where the intensity of light is sufficient to achieve biostimulation, but not sufficient to achieve a hyperthermic temperature (i.e., the temperature is less than 38°C) as indicated in Figure 2. It is to be appreciated that the effect of biostimulation is weaker in depth region 230 than in depth region 240 due to the absence of hyperthermia in depth region 240.

Biostimulation and photohyperthermia according to the second aspect of the invention, may be achieved using a conventional small area of irradiation (e.g., a round area having a spot size less than 10 mm in diameter), or a larger area (e.g., a round area having a spot size larger than 1 cm^2 , up to 200 cm^2 or more). Generally, the larger the area, the deeper depth regions 230 and 240 extend below surface 115 due to a reduction in the effect of scattering. For example, irradiation with a wavelength of 600-1250 nm at a flux $0.1\text{-}1.0 \text{ W/cm}^2$, and a spot size 1-200 cm after 80 seconds of exposure will

achieve heating and biostimulation to a depth up to 30 mm and biostimulation (without hyperthermia) from 30 mm - 50 mm.

Figures 6 and 7 present graphical data for achieving a selected temperature profile using exemplary wavelengths of monochromatic light without skin cooling (Figure 6) and with parallel skin cooling (Figure 7). Specifically, the numbered entries in Tables 2 and 3 describe the flux at the skin surface and the time necessary to achieve a correspondingly-numbered steady-state temperature profile in Figures 6 and 7, respectively. It is to be understood that the wavelengths in Figures 6 and 7 are exemplary and light of any suitable wavelength may be used to achieve hyperthermia. Exemplary profile 7, in Figure 6, illustrates hyperthermia in a volume of tissue (e.g., volume of tissue 260) which extends from the surface of skin (illustrated as skin depth 0 in Figure 6). Sources corresponding to exemplary profiles 1-6 and 8-10 may also be used to achieve hyperthermia in a volume of tissue (e.g., volume of tissue 260) which extends from the surface of skin by suitably increasing the power of source to achieve a greater flux.

Table 2. Flux and minimum exposure time to heat body up to +42°C without active cooling.

N	Wavelength, nm	Flux, W/cm ²	Heating time, s
1	800	0.683	209
2	925	0.573	193
3	960	0.466	206
4	1060	0.535	187
5	1208	0.383	189
6	1240	0.377	199
7	1440	0.491	208
8	1540	0.354	219
9	1730	0.359	212
10	2200	0.425	214

Table 3. Flux and minimum exposure time to heat skin up to +42°C with active cooling of skin surface at the temperature +36°C.

N	Wavelength, nm	Flux, W/cm ²	Heating time, s
1	800	1.76	41
2	925	1.135	36
3	960	1.085	47
4	1060	0.967	35
5	1208	0.643	37
6	1240	0.685	41
7	1440	3.39	170
8	1540	1.21	132
9	1730	0.996	124
10	2200	2.335	170

5 Figure 12A illustrates the temperature at the skin surface as a function of time of exposure to a 800 nm radiation at a flux of 680 mW/cm², wherein the beam has a diameter larger than 2.5 cm. The data illustrated in Figure 12A was calculated using a computer model including the following assumption: a 3 mm skin thickness, a 5 mm subcutaneous fat thickness, muscle extending below the subcutaneous fat, and a body temperature of 37°C. Figure 12B illustrates temperature profiles corresponding to an embodiment of Figure 2 in which the skin surface is cooled and kept to 36°C. The temperature profiles of Figure 12B correspond to the data of Table 3. The data illustrated in Figure 12B were calculated using a computer model including the following assumption: a 3 mm skin thickness, a 5 mm subcutaneous fat thickness, muscle extending below the subcutaneous fat, and a body temperature of 36°C.

Figure 3 illustrates a third aspect of the invention to generate photobiostimulation in a volume of tissue 360 in a depth region 330 below the surface of skin 115 and cooling is applied to the surface of skin 115. Photobiostimulation may be suppressed or reduced in efficacy in volume of tissue 380 in a depth region 320 by cooling surface of skin 115. Volume of tissue 360 is defined by depth region 330, and an area 350. Hyperthermia does not occur in any portion of volume of tissue 360.

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To achieve photobiostimulation (without hyperthermia) in volume 360 with suppressed biostimulation or biostimulation of reduced efficacy in volume 380, a source 310 projects radiation in a 1-10,000 mW/cm² range and cooler 312 applies cooling at the skin surface to decrease temperature in a volume 380 defined by area 350 and depth region 320 to a hypothermic temperature (i.e., a temperature below normal body temperature). Cooler 312 can be any suitable cooler, for example a fan, flow of cold (below 36 °C) fluid (i.e., liquid or gas), cryogenic spray, vaporizing cream, cold plate or window in contact with skin, or other contact or non-contact cooler.

The temperature of the target region may be reduced to approximately 0-36 °C, or about 10-36 °C, or about 15-36 °C, or about 20-36 °C, or about 28-36 °C. Hypothermia may be used to protect the skin from damage caused by heat generated by irradiation. Additionally, by reducing the temperatures, the efficacy of biostimulation may be reduced or biostimulation may be suppressed. A reduction in efficacy may be due to a variety of factors, including reduced microcirculation of blood, and slowing down of relevant biochemical reactions with lower temperature. Cooling of the target region can slow down metabolic and physiological processes and reduce the oxygen need of cells, particularly neurons. Care must be taken to prevent frostbite, which can occur at temperatures below 0 °C. In addition, the total body temperature (i.e., rectal temperature) should not be reduced below about 28 °C, the point at which the ability to regain normal temperature is lost. In some embodiments, temperatures below 0 °C can be used on a small target area for short time periods.

In some aspects, hypothermia may result in increased biostimulation. Reducing temperature leads to the generation of specific cold shock proteins, phase transfer in lipid structure of cell membrane or fat cells. These changes to the target region can increase the efficacy of biostimulation for the treatment of specific diseases or cosmetic conditions.

For example, to achieve biostimulation without hyperthermia, irradiation with a wavelength of 500-1200 nm at a flux 1-1,000 mW/cm² and beam area of 0.8 cm² (e.g., a round area yielding a spot size at the target area of greater than 1 cm²), for a time interval greater than 60 seconds will achieve biostimulation to a depth of 25 mm. If the skin surface 115 is kept at 0-32 °C, hypothermia will exist in a volume 380 above

treatment region 360 resulting in reduced or suppressed biostimulation in this volume. In some embodiments, hypothermia can increase biostimulation.

Figure 4 illustrates another aspect of the invention in which a volume of tissue 460 is heated such that biostimulation is applied to a hyperthermic volume of tissue 460, wherein volume of tissue 460 is at a selected depth below the surface of the skin 115, and volumes (without hyperthermia) 465, 470 are located above and below volume 460, respectively. Hyperthermia is suppressed in volume 465 by a cooler 412 and volume 470 is not heated sufficiently to achieve hyperthermia. Volume of tissue 460 is defined by depth region 430, and an area 450.

To achieve photobiostimulation and hyperthermia in volume 460, a source 410 projects radiation in a 100-10,000 mW/cm² range and cooler 412 applies cooling at the skin surface (0-30 °C) to suppress hyperthermia at surface 115. Treatments, such as the treatment of Figure 4, may be achieved using a biostimulative source applied using a relatively large area of illumination (e.g., a round area having a spot size with a diameter larger than 1 cm-200 cm or more). Heating a volume of tissue wherein the volume is a selected depth below the surface of the skin is described in U.S. Provisional Application 60/389,871, filed June 19, 2002, entitled "Method and Apparatus for Photothermal Treatment of Tissue at a Depth," the substance of which is incorporated by reference herein.

For example, to achieve photobiostimulation and hyperthermia according to the present aspect of the invention, irradiation with a wavelength of 500-1250 nm at a flux 100-10,000 mW/cm² and a area of irradiation of 0.8 cm² after 60 seconds of exposure will achieve biostimulation in a range of depths 0-50 mm below the skin surface, and if the skin surface is kept at 0-30 °C hyperthermia will be achieved in a range of depths 0.2-30 mm below the skin surface. Treatments according to this aspect of the invention may be achieved using a relatively large area (e.g., a round area having a spot size diameter 1 cm-200 cm or more).

Figure 5 illustrates another aspect of the invention in which a volume of tissue 560 is heated by source 510 such that enhanced biostimulation occurs in this hyperthermic volume of tissue, volume 560 being located a selected depth below the surface of the skin 115. The skin surface 550 can be cooled by the cooling source 512 either simultaneously or sequentially to the heating. Biostimulation (without

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hyperthermia) occurs in a volume 540 located below volume 560. A volume of tissue 560 is defined by depth region 530, and an area 550.

As described above with reference to Figure 4, the efficacy of biostimulation is suppressed in a volume 520 adjacent to skin surface. However, according to this aspect of the invention, hyperthermia occurs only in volume 560.

For example, to achieve photobiostimulation and hyperthermia according this aspect of the invention, irradiation with a wavelength of 500-1250 nm at a flux 100-10,000W/cm² and an area of irradiation greater than 0.8 cm² after 60 seconds of exposure will achieve biostimulation in a range of depths 0.1-50 mm below the skin surface, and if the skin surface is kept at 0-30 °C, hyperthermia will be achieved in a range of depths 0.2-30 mm below the skin surface. Treatments according to this aspect of the invention may be achieved using a relatively large area (e.g., a round area having a spot size 1 cm-200 cm or more).

Figure 7 depicts graphical data and corresponding tabular data, for achieving a selected temperature profile using exemplary wavelengths of monochromatic light, in which the skin surface is cooled to a temperature of 10 °C and photobiostimulation is suppressed in a region of tissue adjacent the skin surface. Specifically, the numbered entries in Table 3 describe the flux at the skin surface and the time necessary to achieve a correspondingly-numbered steady-state temperature profile in Figure 7. It is to be understood that the wavelengths in Figures 6 and 7 are exemplary and light of any suitable wavelength may be used to achieve hyperthermia, and biostimulation.

Although the above discussion describes static (i.e., non-moving) radiation sources, the desired combination of photobiostimulation and photohyperthermia can be achieved by moving an output head of a radiation source across the surface of the skin so as to achieve the desired tissue temperature and/or deliver the desired amount of light to achieve biostimulation. The head may be moved over each skin surface area a single time or multiple times as required to achieve the desired therapeutic effect. Moving a source across the surface of the skin can be used to achieve hyperthermia in a volume of tissue due to the relatively long thermal relaxation time of bulk tissue. Further details regarding moving sources and heating of tissue is given in U.S. Pat. No. 6,273,884 B1 , entitled "Method and Apparatus for Dermatology Treatment," to Altshuler et al., issued August 14, 2001, the substance of which is hereby incorporated by reference.

Photobiostimulation can be achieved by moving the source output head across the skin at a rate and/or for a number of iterations such that the desired number of photons are delivered to the treatment volume of tissue.

5 The above aspects of the invention are directed to applying biostimulation to a hyperthermic and/ or a hypothermic volume of tissue. For these aspects, the heating source and biostimulative radiation source may be applied simultaneously, and for some embodiments may be the same source, or the heating source may be discontinued during application of the biostimulative radiation, or the heating source may be applied in a
10 reduced amount to maintain the hyperthermic condition.

 Figure 8 is a schematic diagram of a light projection system 800 appropriate for use with aspects of the present invention according to Figure 2 above. Light projection system 800 is composed of a radiation source 802 and a lens system 820. The radiation source may be any suitable narrowband source for generating hyperthermia and
15 biostimulation according to an embodiment of the invention described above with reference to Figure 2. For example, the source may be a laser (e.g., a continuous-wave diode laser, emitting at 805 nm with output power of 90 W) or an array of lasers, an LED (or an array of LEDs) or a lamp. The radiation from source 802 may be coupled to an optical fiber 803 (e.g., a 1 mm core quartz-polymer fiber) or a suitable fiber bundle,
20 which is coupled on its proximal end to light source 802.

 Lens system 820 may be any suitable lens system for transmitting light from source 802 to a patient's skin surface with a flux and beam size as described above with reference to Figure 2. In one embodiment, lens system 820 includes a negative lens 806, and a positive lens 808 that forms a collimated output beam 810. In one embodiment of
25 system 800, lens 806 is a refractive lens, and lens 808 is a Fresnel lens. A Fresnel lens may provide safety effects (e.g., a more uniform illumination pattern due to a reduction of speckle). As an example of this embodiment, lens 806 is a negative lens having a focal length of 25 mm and a diameter of 25 mm, and lens 808 is a 152 mm diameter Fresnel lens with a focal length 152 mm; and the distance between radiation source 802
30 and lens 806 is 20 mm, and the distance between the lenses 806 and 808 is 105 mm.

 According to some aspects of the invention, output beams having larger diameters are used to direct narrowband light (e.g., laser or monochromatic filtered light) more deeply into the dermis and subcutaneous tissue than conventional low power

laser sources emitting small beam sizes. For example, according to the above exemplary embodiment of lens system 820, for a 90W source, lens system 820 produces an output beam 810 having a diameter of 160 mm, and has an output flux of 200 mW/cm² to 2000 mW/cm² (at a distance of 23 cm from lens 808).

Figure 13A is an exemplary embodiment of a light projection system 1300 according to aspects of the present invention, enabling one to practice the invention according to the scenarios illustrated in Figures 1 and 3, 4, and 5. For example, projection system 1300 may be any system that provides an output beam having suitable diameter and flux at skin surface 1350. In one embodiment, projection system 1300 includes an optical source 1302, and optical elements 1304, 1306, 1312, 1314, and 1308. One exemplary set of lens parameters is given in Figure 13B.

Optical elements 1306 and 1314 may be movable along optical axis 1301 such that output beam 1310 has a variable diameter. For example, lenses 1306 and 1314 may be connected to a rigid frame 1316 (e.g., a translation stage), allowing synchronous movement of the lenses 1306 and 1314 along optical axis 1301 of the system 1300. Such movement provides variation in the beam width of the output beam 1310 (e.g., spot size is changed) and provides a corresponding variation in flux on skin surface 1350. For example, the system 1300 can provide continuous variations of a spot size between 4 cm and 8 cm, with the flux varying through a corresponding range of 7 W/cm² to 2 W/cm² (assuming source 1302 is a 90 W source). It is to be appreciated that by suitable selection of elements and source 1302, lens system 1300 may be designed to achieve any output beam 1310 as described herein, and any suitable output density as described herein.

System 1300 includes at least one air tube 1318, connected on its proximal ends to a cold or hot air source (not shown) and providing, at its distal end, an airflow 1320 directed at patient's skin 1350. For example, a total air flow from the at least one air tube 1318 may be at least 50 m³/min to vary air temperature in accordance with the embodiments illustrated in Figures 3 -5 (e.g., the temperature will be between 0 °C and 45 °C at skin surface 1350); and in accordance with Figure 1, a hot air flow will be provided to skin surface 1350. By varying the beam diameter and the air temperature, all regimens of Figures 1, 3, 4, and 5 can be realized using the system of Figure 13A.

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While Figures 8 and 13A were described by specifying beam diameters, it is to be appreciated that by appropriate aperturing, any shape beam may be achieved.

Figure 9A is a first exemplary embodiment of a light projection system 900 for forming substantially uniform illumination over a non-flat surface 950, such as a patient's head or thigh. A collimated beam from a source 902 is directed onto a beam splitter 904 to form a plurality of beam portions 905a-c. In the illustrated embodiment, beam splitter 904 forms three component beam portions 905a, 905b, and 905c; however, a light projection system 900 having two or more beam portions may provide advantages. Beam portion 905b is directed directly on the surface 950, and beam portions 905a and 905c are directed onto mirrors 910a and 910b, respectively, and then redirected to the sides of the surface 950. The clear apertures of beam splitter 904, mirrors 910a, 910b or additional apertures can be selected to achieve any desired area of irradiation on surface 950 (e.g., 1–200 cm²). Light projection system 900 may be modified (e.g., to treat one side of a patient's face) by blocking one of beams 910a and 910b.

Figure 9B is a schematic of one example of a beam splitter 904. Beam splitter 904 is a prism having two flat surfaces 912a, 912b appropriately angled to direct light onto mirrors 910a, b, and a surface 913 having a negative power to expand light onto the front portion of surface 950.

Figure 10 is a schematic of a second exemplary embodiment of a light projection system 1000 for forming substantially uniform illumination over a non-flat surface 950. Light projection system 1000 has a head 1002 adapted to project light in two directions. A first portion of light 1006 is directed in a first direction onto a curved reflector 1004 and then onto surface 950, and a second portion 1008 is directed in a second direction onto a surface 950. First portion of light 1006 is projected onto reflector 1004 directly or through an optical element (lens 1005), and second portion 1008 projected directly onto surface 950 or through an optical element (e.g., lens 1009).

Reflector 1004 may have any suitable shape for achieving a selected treatment. In some embodiments, reflector 1004 is designed such that center 1010 of surface 950 (e.g., the center of a patient's head) is located substantially at the center of curvature of reflector 1004. Alternatively, reflector 1004 may have an elliptical curvature and center 1010 of surface 950 (e.g., the center of a patient's head) is located substantially at a

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focus of reflector 1004 and the center 1010 of surface 950 is located at a second focus of reflector 1004. In one embodiment, reflector 1004 can be a diffuse reflector.

5 Projection system 1000 may include a control module 1016 comprising an electrical power source and control electronics. Additionally, a light source (not shown) may be mounted in head 1002; alternatively, a light source may be mounted in module 1016 and delivered to head 1002 by an optical fiber or a bundle of fibers. Light sources can be narrow band (e.g., diode lasers, LEDs), or broadband (e.g., filtered lamp). Alternatively, light sources may be a combination of narrow band and broadband
10 sources. Optionally, in accordance with the embodiments described above, cold or hot air can be directed on the surface from head 1002 onto surface 950.

Figures 11A, 11B, and 11C are schematics of a third example of an embodiment of a light projection system 1100 for forming substantially uniform illumination over a non-flat surface 950 in which a rotatable head 1102 reflects light from a surface 1110
15 onto surface 950. In Figure 11A, rotatable head 1102 is positioned such that light is directed onto the front portion of surface 950. In Figure 11B, rotatable head 1102 is positioned such that light is directed onto a first side portion of surface 950. In Figure 11C, rotatable head 1102 is positioned such that light is directed onto a second side portion of surface 950.

20 Optionally, head 1102 may be omitted, and replaced with a source mounted on surface 1110 such that the source is moved to various positions on surface 1110 to direct light onto each of the portions indicated in Figures 11A-11C. Alternatively, a plurality of sources can be mounted on surface 1110 and selectively illuminated to direct light onto each of the portions.

25 In another aspect, the present invention provides a feedback mechanism for controlling the temperature of a target region within a selected range while causing biostimulation within that target region and/or a volume above, below, or adjacent to the target region. The feedback mechanism can be used to control both heating and cooling of the target region. With reference to Figure 14, in an exemplary embodiment, the
30 source of electromagnetic radiation 1410 generates radiation for illuminating a portion of the surface area of the patient's skin 1450 so as to irradiate a volume of the patient's tissue 1460 that extends from the surface of the skin 1415 to a given depth 1430 below the skin. The radiation includes one or more wavelength components that can cause

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biostimulation of the irradiated tissue volume 1460. Another source 1420, for example, a separate source of electromagnetic radiation, controls the temperature of the irradiated volume, e.g., by illuminating the skin surface area 1450 with radiation having
5 wavelength components suitable for heating tissue. A sensor 1470, for example, an optical pyrometer, measures the temperature of the illuminated skin portion 1450, and transmits the measured temperature to a feedback control circuitry 1480. The feedback circuitry 1480 compares the measured temperature with at least one threshold temperature, and transmits feedback signals, if needed, to the source 1420 based on this
10 comparison. For example, if the measured temperature exceeds a pre-defined upper threshold, such as when the portion of the surface area of the patient's skin 1450 is heated to cause hyperthermia, the feedback circuitry can transmit a signal to the source 1420 to lower the amount of heat delivered to the skin portion 1450. Alternatively, the feedback circuitry can instruct the source 1420 to increase the amount of heat delivered
15 to the skin portion 1450 if the measured temperature falls below a pre-defined lower threshold. In this manner, the temperature of the illuminated skin portion 1450, and consequently that of the target region 1460, can be actively maintained within a selected range about an operating temperature. For example, the above feedback mechanism can ensure that the operating temperature remains within ± 1 °C of 39 °C. A variety of
20 sensors and feedback circuitry suitable for use in the practice of the invention are known in the art.

Those skilled in the art will appreciate, or be able to ascertain using no more than routine experimentation, further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what
25 has been particularly shown and described, except as indicated by the appended claims. The contents of all references, patents and published patent applications cited throughout this application, are incorporated herein by reference.

CLAIMS

1. A device for biostimulating a patient's target region, comprising:
5 a first source for generating electromagnetic radiation having one or more wavelength components suitable for causing biostimulation in said target region, a radiation guidance device optically coupled to said source for delivering said radiation to the target region, and
a second source in communication with said target region for controlling a
10 temperature of said target region in order to modulate efficacy of biostimulation caused by said electromagnetic radiation.
2. The device of claim 1, wherein said first source generates radiation having a
15 bandwidth less than about 100 nm.
3. The device of claim 1, wherein said first source generates a substantially monochromatic radiation.
4. The device of claim 1, wherein said first source generates radiation having one or
20 more wavelength components in a range of about 380 nm to about 1250 nm.
5. The device of claim 1, wherein said second source comprises a source of electromagnetic radiation generating radiation suitable for heating said target region so as to enhance the efficacy of biostimulation.
25
6. The device of claim 5, wherein said second source generates radiation having one or more wavelength components in a range of about 380 nm to about 2700 nm.
7. The device of claim 5, wherein the radiation guidance device comprises a lens
30 system for delivering the biostimulating radiation from the first source to the target region.
8. The device of claim 5, wherein said lens system comprises a Fresnel lens.

- 34 -

9. The device of claim 5, further comprising an optical fiber coupled at an input thereof to said first radiation source and an output thereof to said lens system so as to direct light generated by said radiation source to said lens system.

5

10. The device of claim 5, wherein said lens system comprises at least one movable lens to allow adjusting a cross-sectional area of a radiation beam generated by said first source for irradiating said target region.

10

11. The device of claim 1, wherein said radiation guidance device comprises a beam splitter adapted to receive a radiation beam from said first source in order to generate a plurality of beam portions, and one or more reflective surfaces optically coupled to said beam splitter to direct one or more of said beam portions to a surface of the patient's skin so as to irradiate said target region.

15

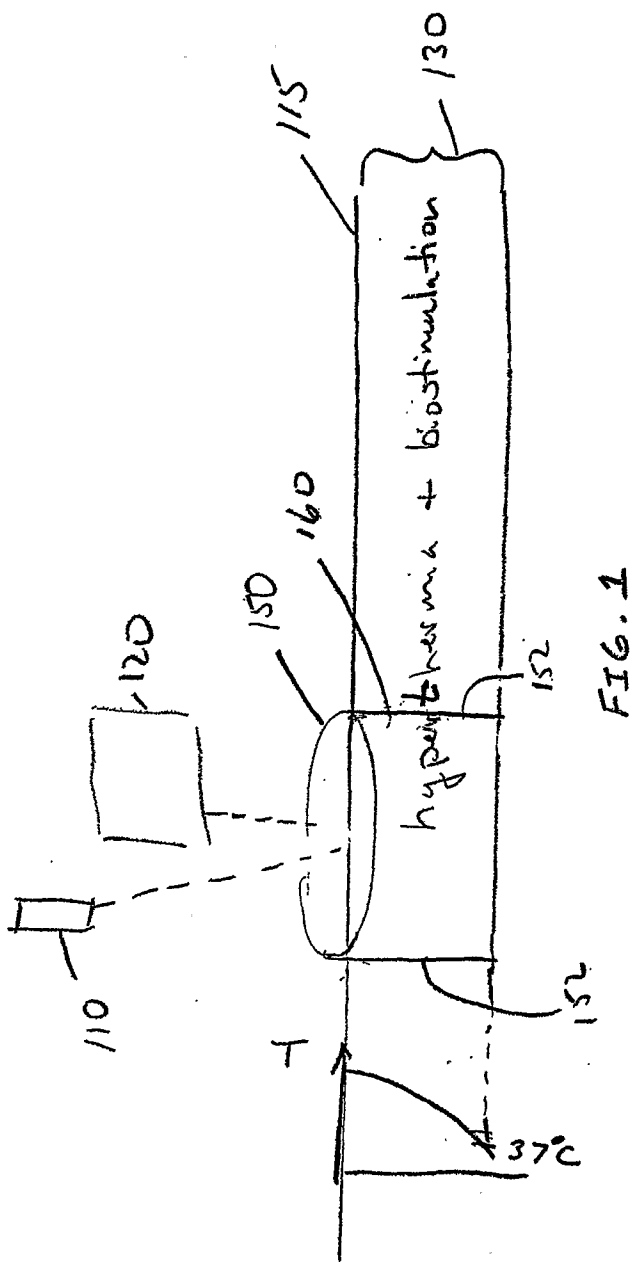
12. The device of claim 11, wherein said reflective surfaces allow a substantially uniform illumination of said skin surface.

20

13. The device of claim 11, wherein said beam splitter comprises a prism.

14. The device of claim 11, wherein at least one of said reflective surfaces exhibits a curved profile.

25



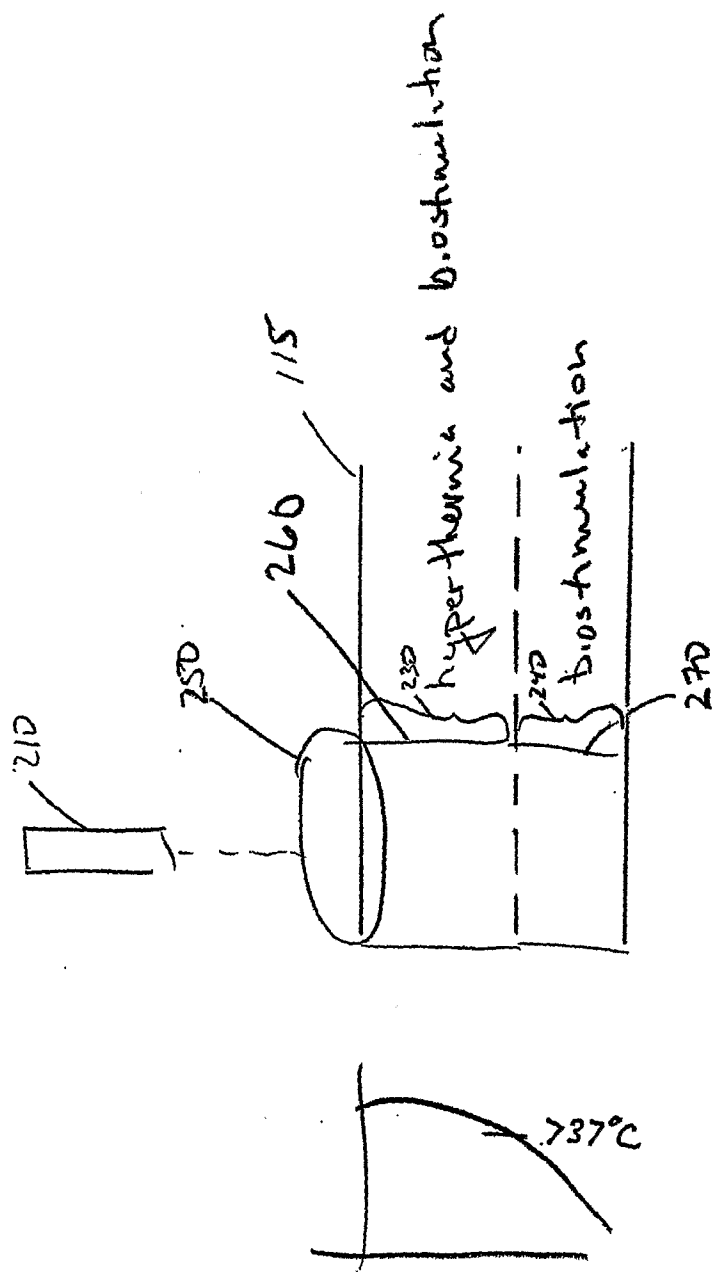


FIG. 2

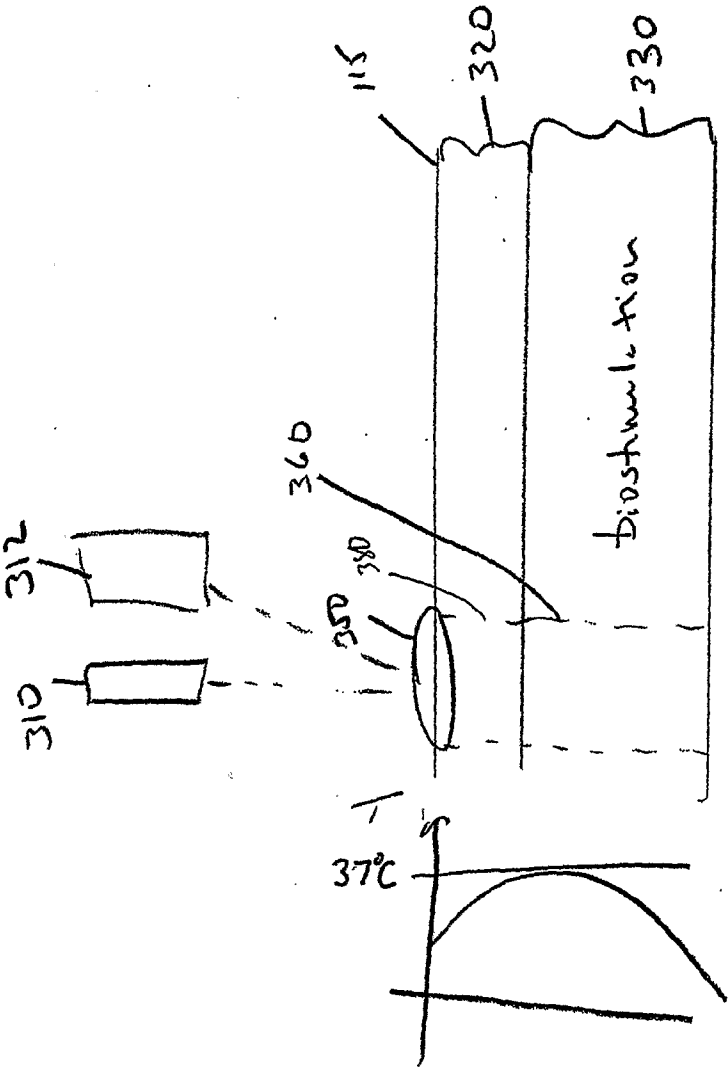


FIG. 3.

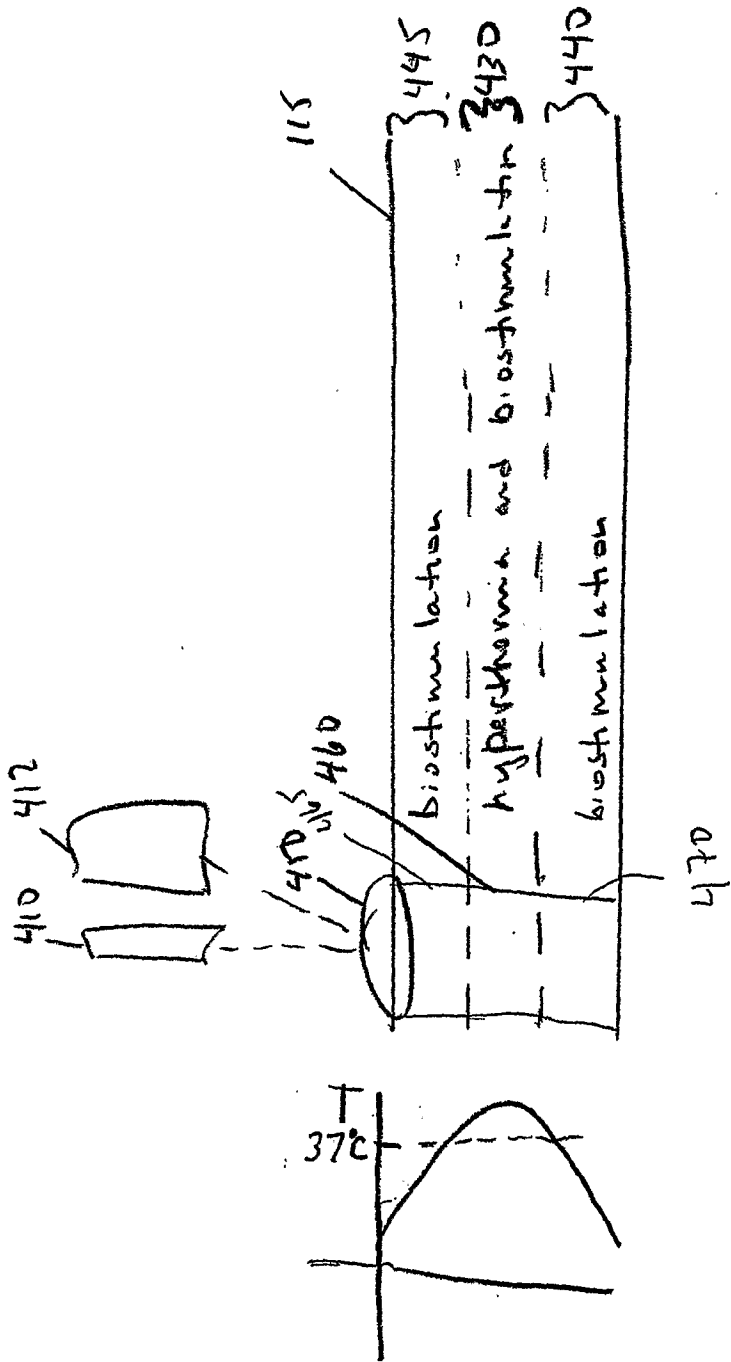


FIG. 4

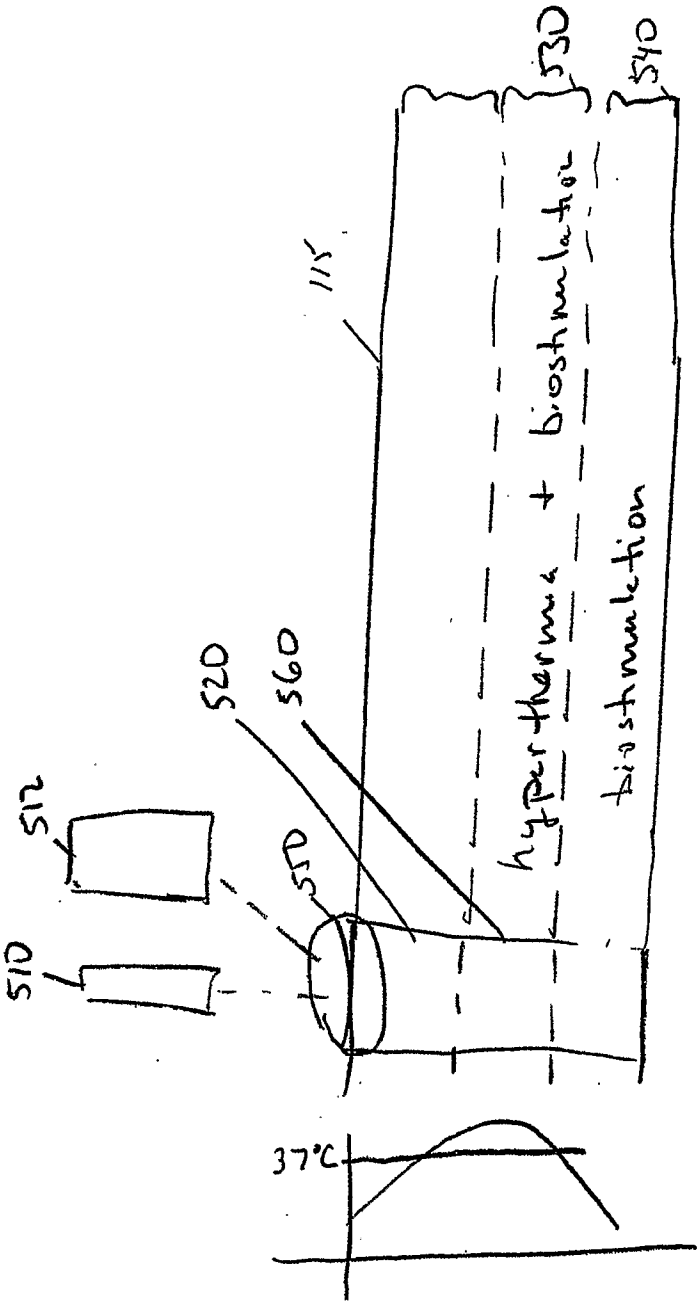


FIG. 5

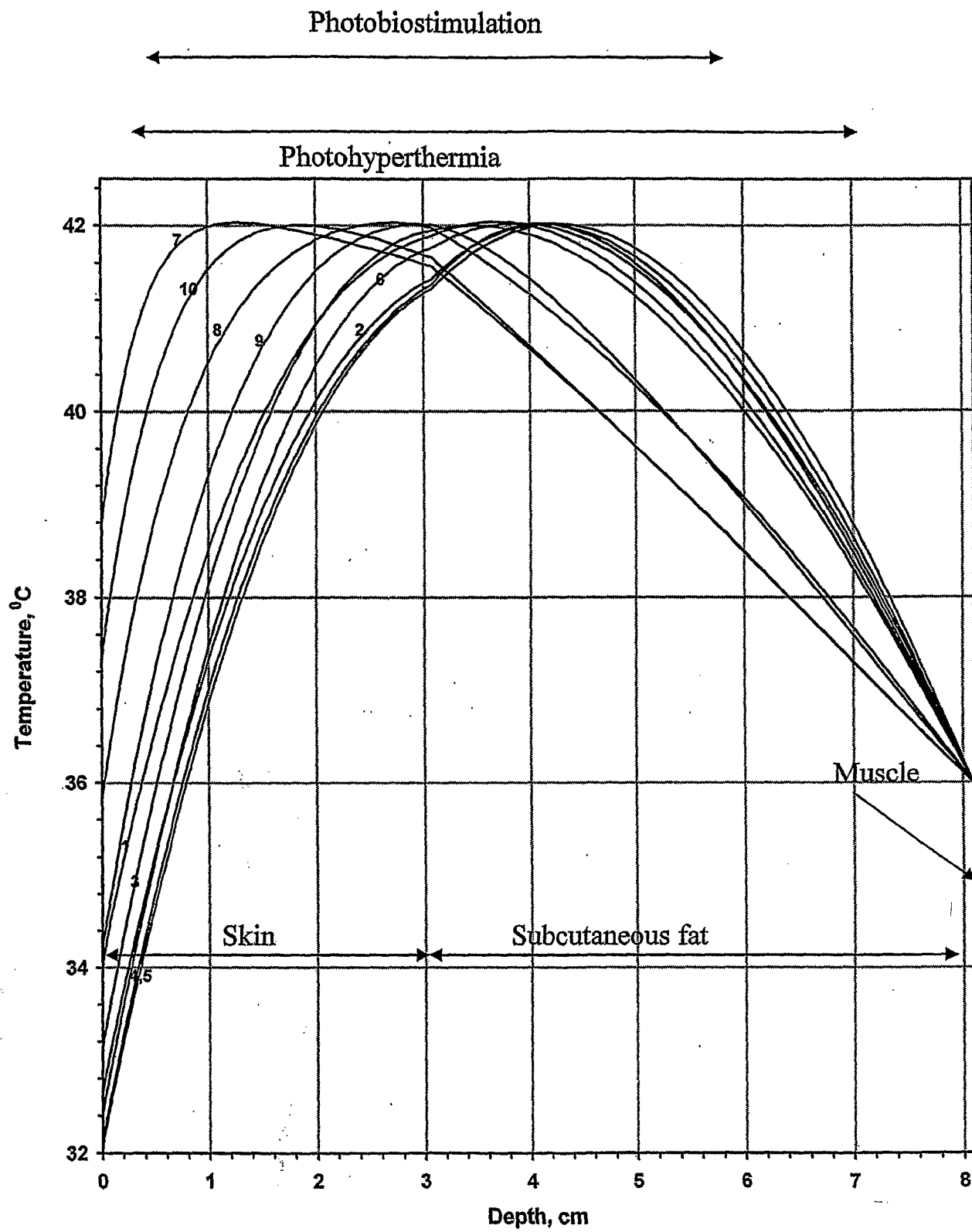


Figure 6

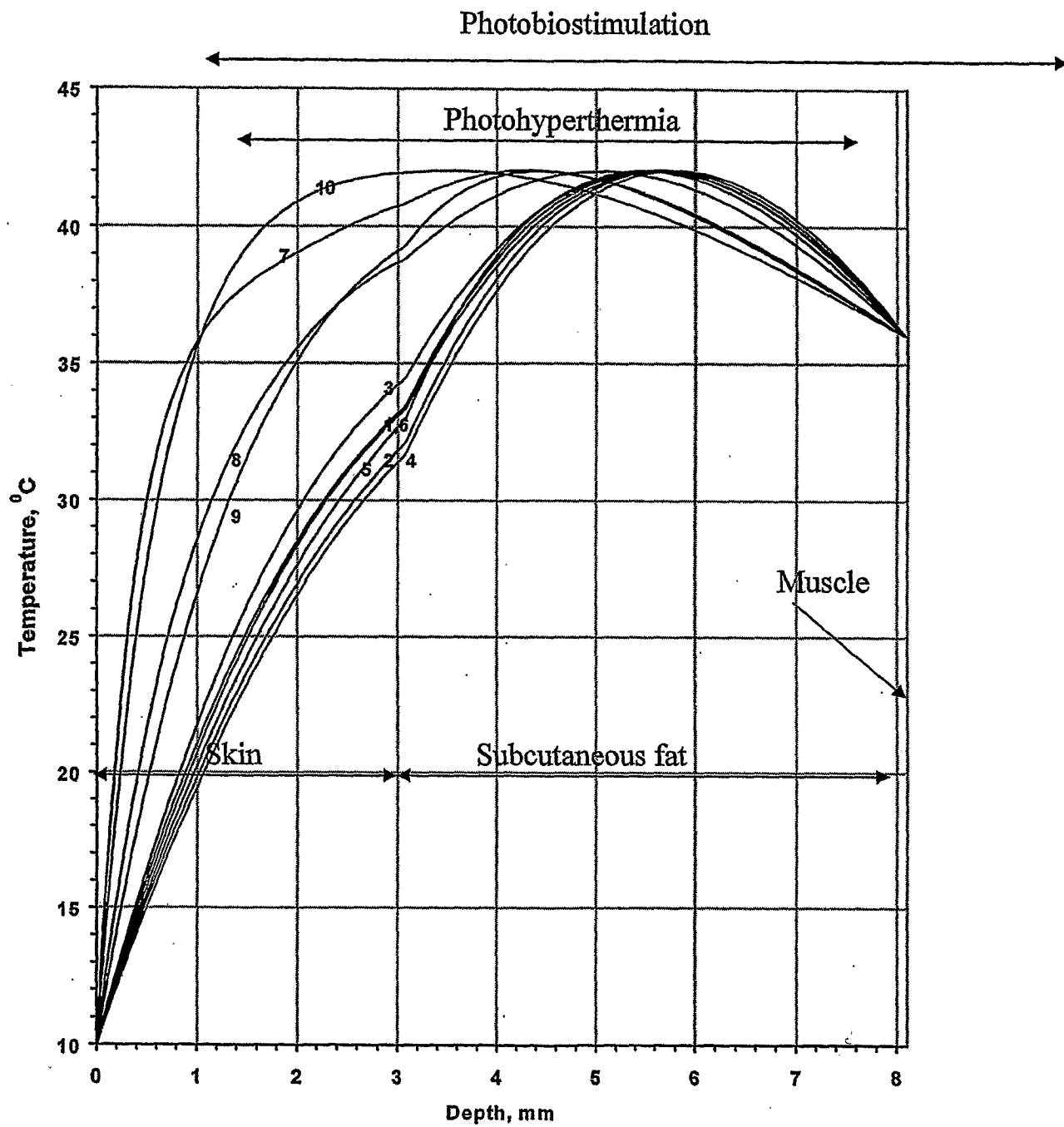


Figure 7

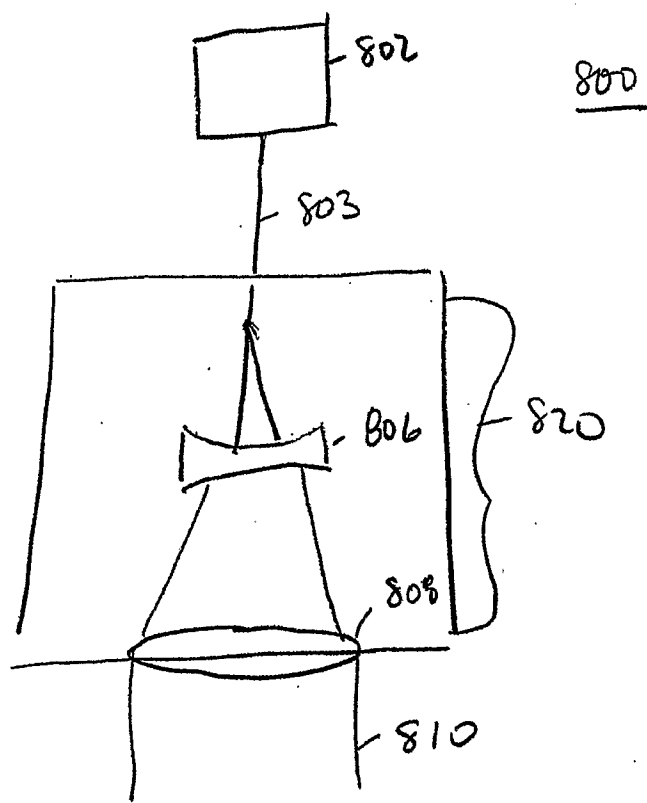


FIG. 8

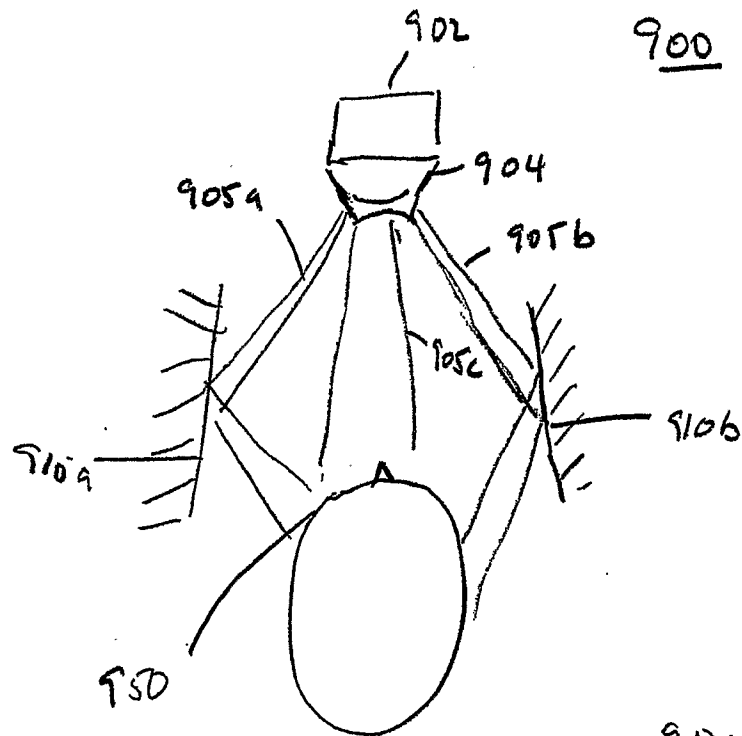


FIG. 9A

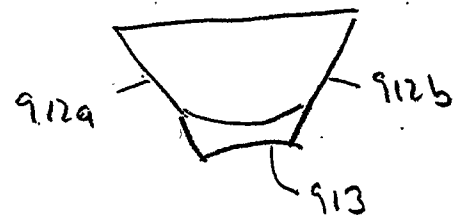


Fig. 9B

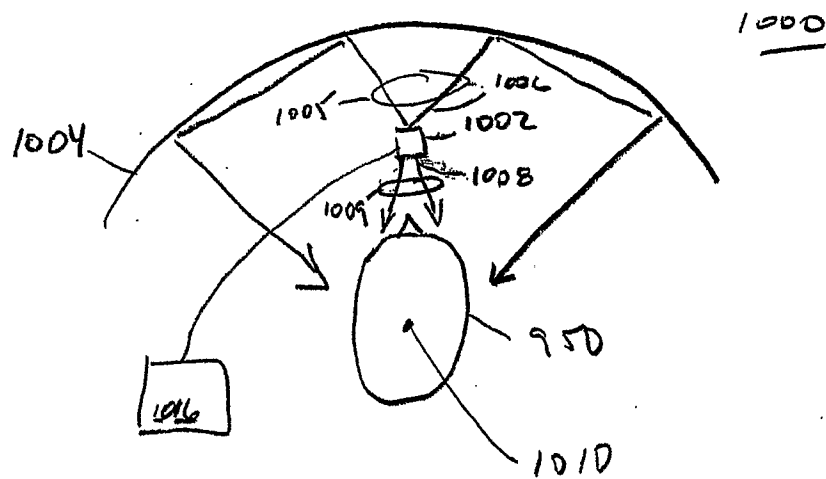


FIG. 10

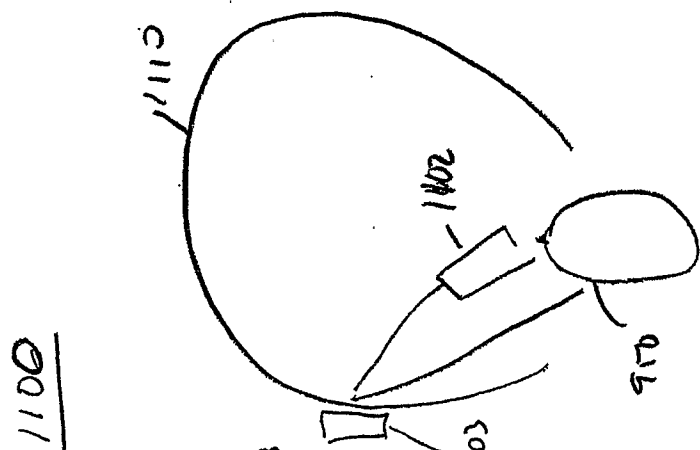


FIG. 11C

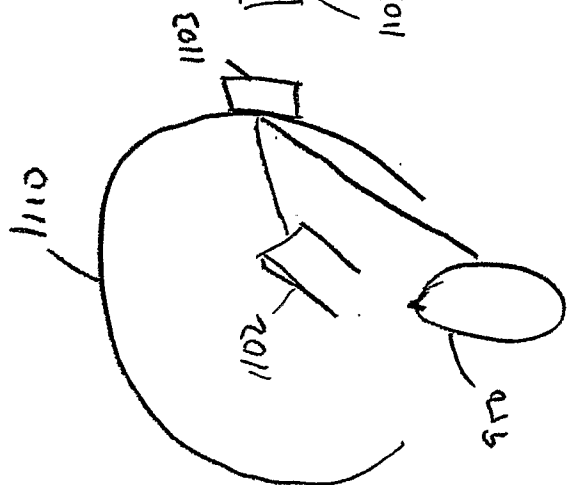


FIG. 11B

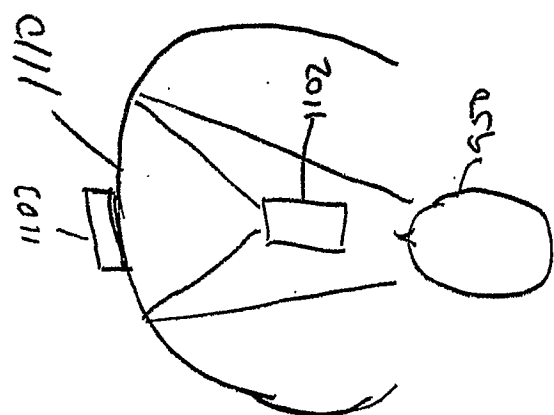
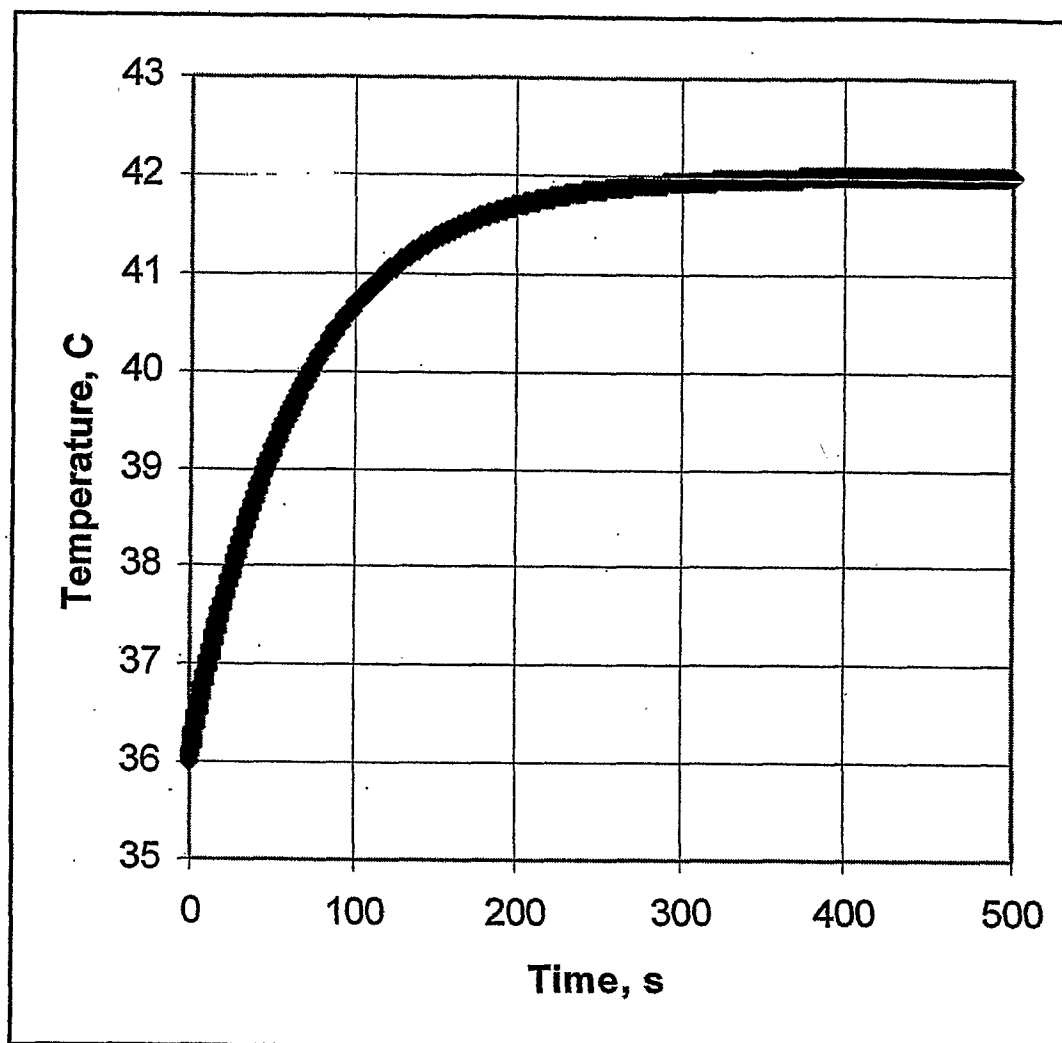


FIG. 11A

**Figure 12A**

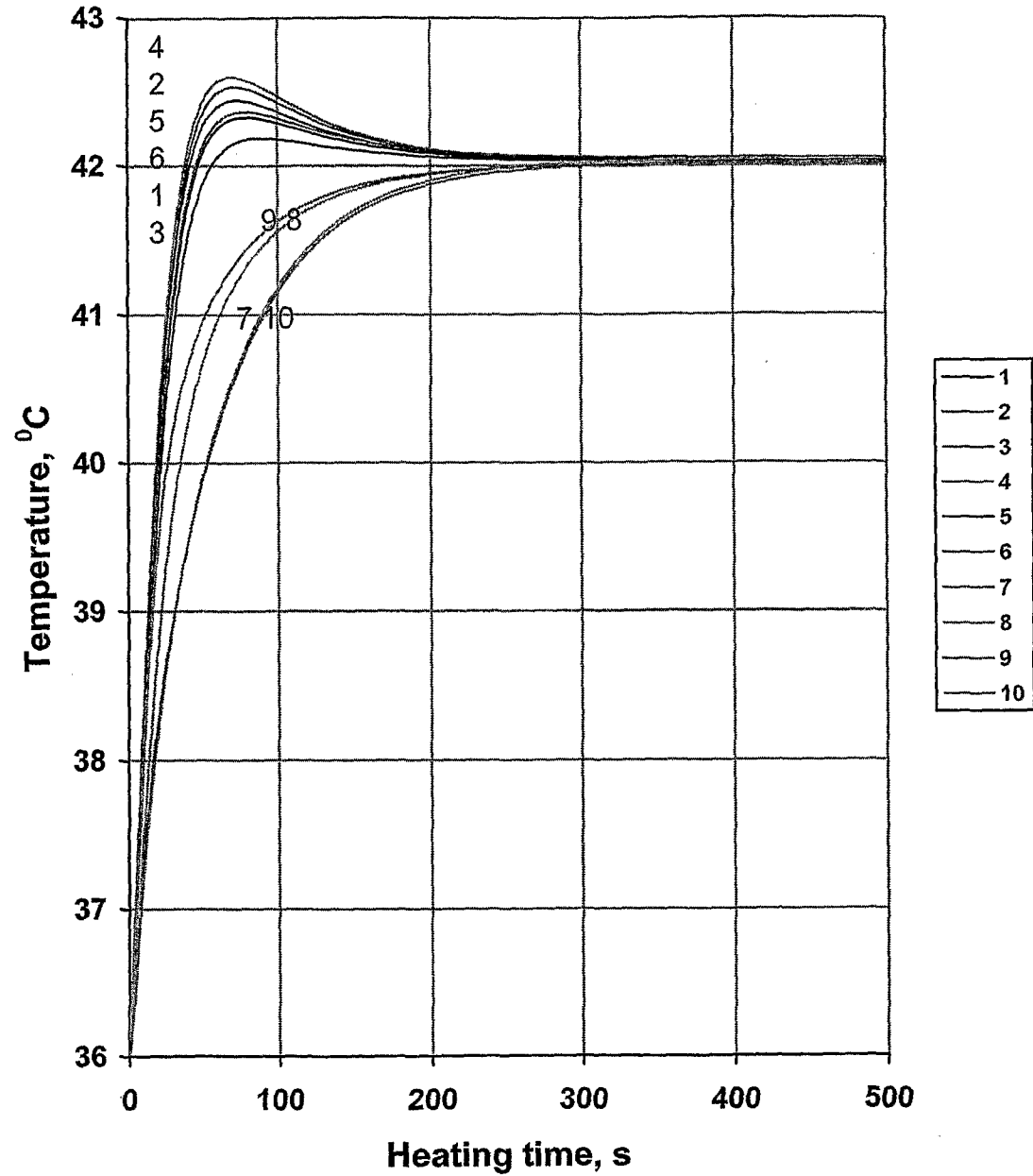
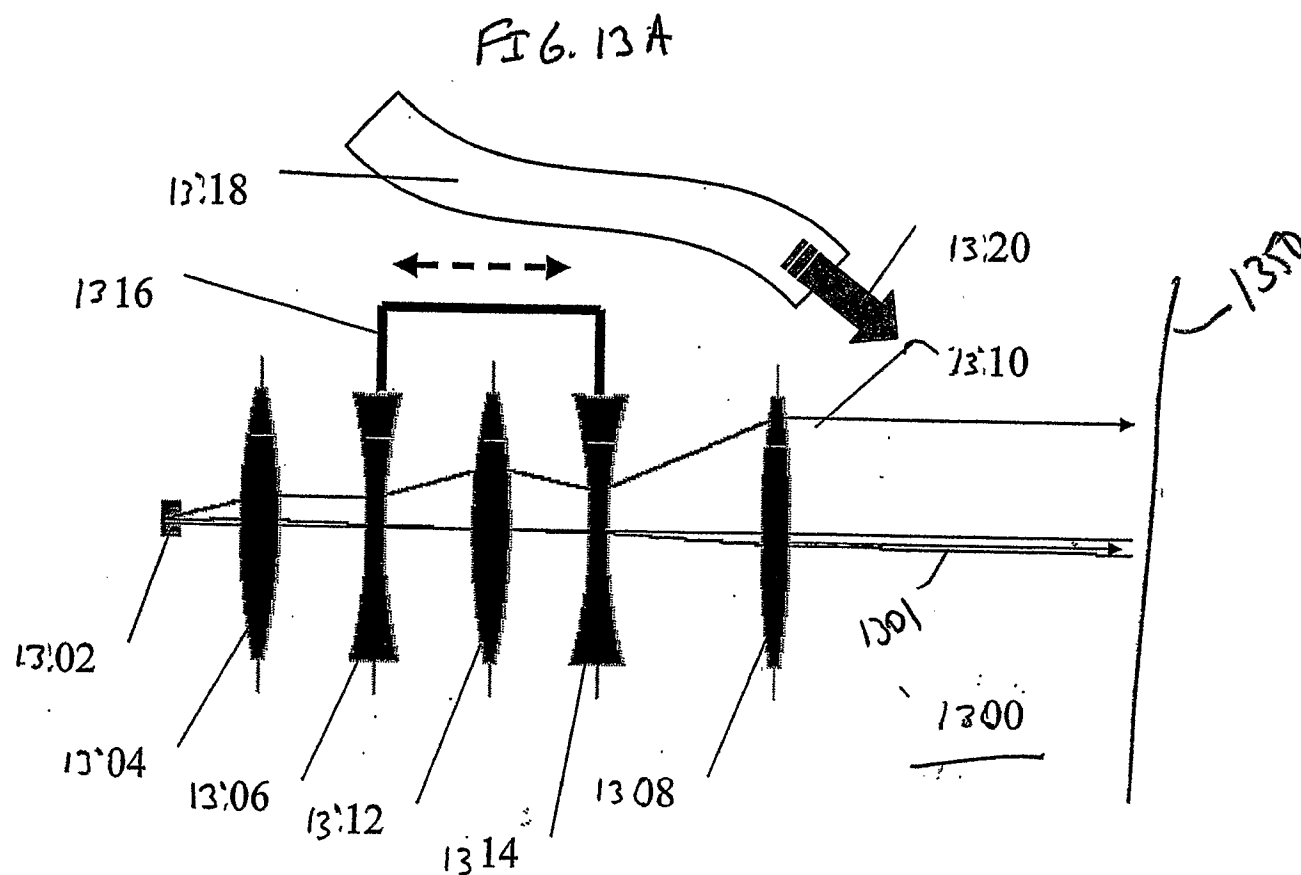


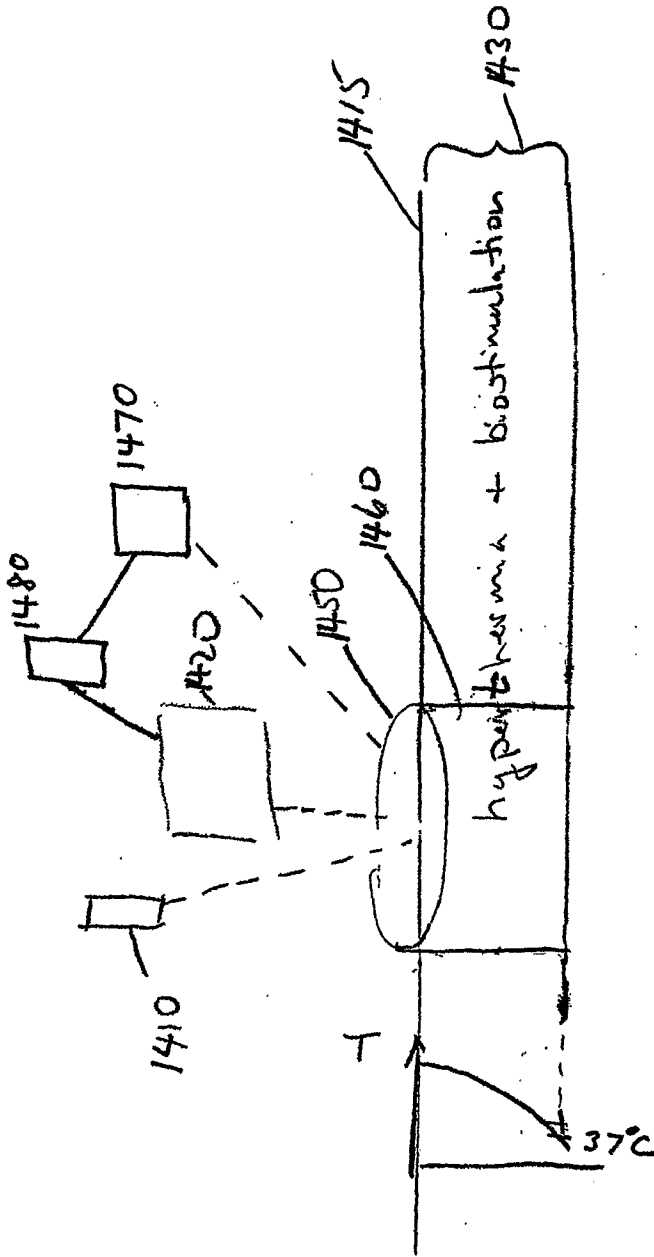
Figure 12B



Lens parameters

Lens	Diameter, mm	Focal length, mm	Distance from 1202, mm
1204	50	70	70
1206	50	-72	149
1212	80	100	232
1214	80	-72	312
1208	80	200	396

FIG. 13B



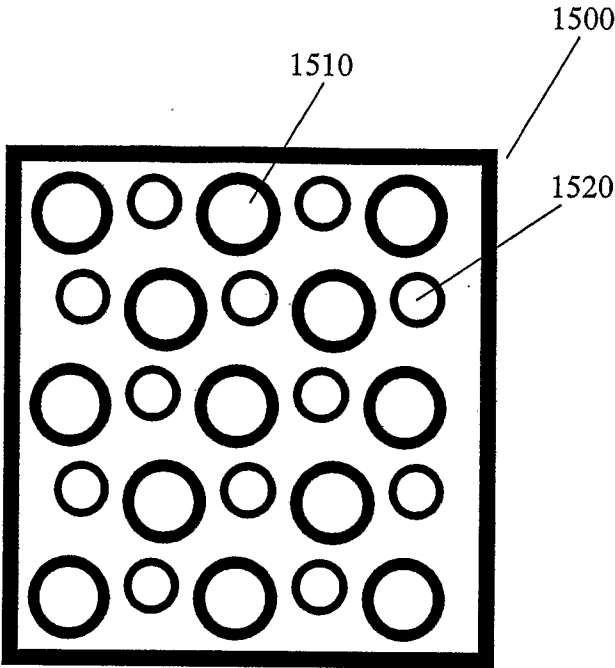


Figure 15

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/31774

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N5/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 814 008 A (CHEN JAMES C ET AL) 29 September 1998 (1998-09-29) abstract column 2, line 55 -column 2, line 67 column 4, line 42 -column 8, line 56; figures 1-8	1-6
Y	the whole document ----	7-14
X	US 6 319 274 B1 (SHADDUCK JOHN H) 20 November 2001 (2001-11-20)	1-4
Y	column 7, line 64 -column 9, line 27 column 12, line 47 -column 12, line 11 ----	7-14
X	US 6 214 034 B1 (AZAR ZION) 10 April 2001 (2001-04-10) abstract	1-6
Y	column 1, line 18 -column 16, line 25 ----- -/--	7-14

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

13 January 2004

Date of mailing of the international search report

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Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

BIRKENMAIER, T

INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/026225 A1 (SEGAL KIM ROBIN) 28 February 2002 (2002-02-28)	1-4
A	abstract; figures 1-3 paragraph '0013! - paragraph '0063! -----	5-14
X	WO 01 78830 A (MEDELASER LLC ;CASEY SEAN M (US); GERDES HAROLD M (US)) 25 October 2001 (2001-10-25) the whole document -----	1-9

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/31774

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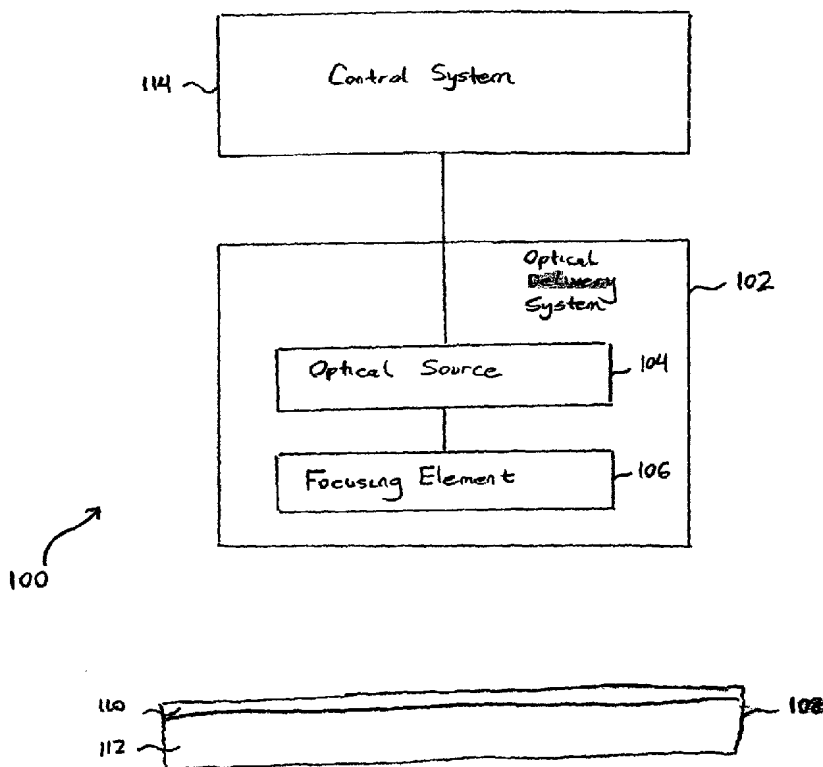
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- (71) Applicant: **RELIANT TECHNOLOGIES, INC.** [US/US]; 260 Sheridan Avenue, 3rd Floor, Palo Alto, CA 94306 (US).
- (72) Inventors: **DEBENEDICTIS, Len**; 153 California Avenue, Unit # F203, Palo Alto, CA 94306 (US). **VOEVOD-KIN, George**; 96 Main Street, Unit # 2, Tarrytown, NY
- (74) Agents: **LIU, Cliff, Z.** et al.; Cooley Godward LLP, 3000 El Camino Real, Five Palo Alto Square, Palo Alto, CA 94306-2155 (US).
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- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,

[Continued on next page]

(54) Title: METHOD AND APPARATUS FOR TREATING SKIN USING PATTERNS OF OPTICAL ENERGY



(57) Abstract: A dermatological apparatus includes multiple light source and optical pathway connections. Each light source is capable of delivering an optical beam through its connected optical pathway to a targeted portion of a human skin. The dermatological apparatus also includes a control system to select and control the light sources to deliver multiple optical beams in a discontinuous pattern and a focusing element to focus the power of the delivered optical beams to multiple discrete treatment zones that are located up to 1.5 mm underneath an outer surface of the targeted portion. The discrete treatment zones have sizes in the range of 10 μ m to 1000 μ m.



SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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METHOD AND APPARATUS FOR TREATING SKIN USING PATTERNS OF OPTICAL ENERGY

FIELD OF THE INVENTION

5 The present invention relates generally to treatment of biological tissues using optical energy. More particularly, the present invention relates to methods and apparatus for treating skin using patterns of optical energy.

BACKGROUND OF THE INVENTION

10 Optical energy has many useful applications for the treatment of skin and other biological tissues. For example, lasers have been used to treat dermatological conditions such as hemangiomas, port wine stains, rosacea, superficial pigmented lesions, and fine wrinkles.

 Current dermatological laser methods and apparatus typically irradiate a relatively
15 large and continuous area of a skin during treatment. However, treatment of such large area can induce an excessive degree of trauma to the skin as well as lead to the development of complications such as hypopigmentation or white spots. Furthermore, the current paradigm of treating a large area can impede normal repair processes of the skin and the flow of nutrients to the treated area, which not only can slow down healing but also may lead to
20 necrosis and scarring. Some of the current methods and apparatus have attempted to overcome these negative effects by including a complex cooling system to cool down the skin in an attempt to reduce excessive heat development at the surface of the skin and resulting trauma to an epidermal layer of the skin. However, such cooling system adds complexity to implementation, often requires that laser power be increased, and also may
25 not provide a desired or uniform level of cooling and trauma reduction of the skin. The combination of non-uniformity in cooling and increased laser power can put the skin at an even greater risk of damage. And, adjusting the fluence delivered by a laser, as specified by current procedures, generally provides an inadequate level of control and often leads to
30 either over-treatment or under-treatment. Over-treatment may cause scarring, and under-treatment may result in no observable improvement in the dermatological condition being treated. Since changes may not be visible for weeks to months after treatment, there is a significant clinical problem associated with either over-treatment or under-treatment.

It is against this background that a need arose to develop the methods and apparatus described herein.

SUMMARY OF THE INVENTION

5 In one particularly innovative aspect, the present invention is directed to a dermatological apparatus. In one embodiment, the dermatological apparatus may comprise a plurality of light source and optical pathway connections. Each light source in the plurality of light source and optical pathway connections is capable of delivering an optical beam through its connected optical pathway to a targeted portion of a human skin. The dermatological apparatus also may comprise a control system to select and control the light sources to deliver a plurality of optical beams in a discontinuous pattern and a focusing element to focus the power of the delivered optical beams to a plurality of discrete treatment zones that are located up to 1.5 mm underneath an outer surface of the targeted portion. The discrete treatment zones have sizes in the range of 10 μm to 1000 μm .

15 In another embodiment, the dermatological apparatus may comprise a plurality of light source and optical pathway connections. Each light source in the plurality of light source and optical pathway connections is capable of delivering an optical beam through its connected optical pathway to an outer portion of a human skin. The dermatological apparatus also may comprise a control system to select and control the light sources to deliver a plurality of optical beams in a discontinuous pattern and a focusing element to focus the power of the delivered optical beams to the outer portion to form a plurality of discrete holes distributed across the outer portion. The discrete holes have sizes in the range of 10 μm to 1000 μm .

25 In a yet another embodiment, the dermatological apparatus may comprise an optical delivery system. The optical delivery system may include an optical source and a focusing element that is optically coupled to the optical source. The optical source is configured to provide optical energy having a wavelength in the range of 400 nm to 20,000 nm, and the focusing element is configured to direct the optical energy in a discontinuous pattern to a targeted portion of a skin.

30 In a further embodiment, the dermatological apparatus may comprise an optical delivery system. The optical delivery system may include an optical source and a focusing element that is optically coupled to the optical source. The focusing element is configured to direct optical energy from the optical source to a targeted portion of a skin. The focusing

element may include an optical lens having a numerical aperture in the range of 0.15 to 1.5, and the optical lens is configured to focus the optical energy to a dermal layer of the targeted portion.

5 In a yet further embodiment, the dermatological apparatus may comprise a housing sized for manipulation by a human hand, an optical source located within the housing, and a focusing element coupled to the housing. The optical source is configured to provide optical energy, and the focusing element is configured to direct the optical energy to a targeted portion of a skin such that a plurality of treatment zones within the targeted portion are exposed to the optical energy. The treatment zones are separated from one another
10 within the targeted portion.

In a still further embodiment, the dermatological apparatus may comprise an optical delivery system. The optical delivery system is configured to direct optical energy in a pattern to a targeted portion of a skin such that a plurality of discrete treatment zones within the targeted portion are exposed to the optical energy. The discrete treatment zones have
15 sizes in the range of 10 μm to 1000 μm .

In another particularly innovative aspect, the present invention is directed to a method of treating a human skin. In one embodiment, the method may comprise providing optical energy. The optical energy has optical parameters to produce a dermatological effect for a targeted portion of the human skin. The method also may comprise directing the optical
20 energy to the targeted portion such that a plurality of discrete treatment zones within the targeted portion is substantially simultaneously exposed to the optical energy.

In another embodiment, the method may comprise providing optical energy and directing the optical energy to an outer portion of the human skin to form discrete holes distributed across the outer portion. The discrete holes have sizes in the range of 10 μm to
25 1000 μm .

BRIEF DESCRIPTION OF THE DRAWINGS

The objectives and advantages of the present invention will be understood by reading the following detailed description in conjunction with the drawings, in which:

30 **FIG. 1** illustrates a block diagram of a dermatological apparatus in accordance with an embodiment of the present invention;

FIG. 2 illustrates an example of a pattern of optical energy that may be directed to a targeted portion of a human skin;

FIG. 3 illustrates another example of a pattern of optical energy that may be directed to a targeted portion of a human skin;

FIG. 4 illustrates a yet another example of a pattern of optical energy that may be directed to a targeted portion of a human skin;

5 **FIG. 5** illustrates a block diagram of a dermatological apparatus in accordance with another embodiment of the present invention;

FIG. 6 illustrates an optical delivery system in accordance with an embodiment of the present invention; and

10 **FIG. 7** illustrates an optical delivery system in accordance with another embodiment of the present invention.

DETAILED DESCRIPTION

Embodiments of the present invention provide an improved dermatological apparatus and method that can be used to treat skin with greater efficacy while reducing complications and healing time. In particular, embodiments of the present invention can be used to treat a wide variety of dermatological conditions such as, but not limited to, acne, birthmarks, excess hair, hemangiomas, dermal melasma, pigmented lesions, rosacea, scars, tattoos, vascular conditions, wrinkles, and so forth. While specific examples of dermatological conditions are given above, it is contemplated that embodiments of the present invention can be used to treat virtually any type of dermatological condition.

20 **FIG. 1** illustrates a dermatological apparatus **100** in accordance with an embodiment of the present invention. The dermatological apparatus **100** includes an optical delivery system **102**, which includes an optical source **104**. The optical source **104** functions to provide optical energy that can be directed to a targeted portion **108** of a skin, such as a human skin. In the present embodiment, the optical source **104** provides optical energy in the form of one or more optical beams, which can be pulsed or continuous wave and coherent or incoherent.

25 In the present embodiment, the optical source **104** may be implemented, at least in part, using one or more light sources, such as laser light sources. For certain applications, the optical source **104** desirably includes multiple laser light sources, which can be arranged in an array, such as a one-dimensional array or a two-dimensional array. A laser light source can provide one or more optical beams having particular optical parameters, such as optical fluence, power, timing, pulse duration, inter-pulse duration, wavelength(s), and so

forth, to produce a desired dermatological effect for the targeted portion **108**. By way of example, a laser light source can provide an optical beam having a wavelength or range of wavelengths between approximately 400 nm and 20,000 nm, such as between approximately 600 nm and 4000 nm. For purposes of non-ablative coagulation of a dermal layer **112** of the targeted portion **108**, a laser light source can provide an optical beam having a wavelength of approximately 1500 nm and an optical fluence incident on the outer surface of the skin between approximately 0.001 Joules/cm² and 10,000 Joules/cm², such as between approximately 0.1 Joules/cm² and 100 Joules/cm². For certain applications, a pulse duration of an optical beam can be approximately equal to or less than a thermal diffusion time constant associated with the targeted portion **108**, which is approximately proportional to the square of the size of a focal spot within the targeted portion **108**. Pulse durations that are longer than the thermal diffusion time constant can be less efficient and cause the focal spot to undesirably grow by thermal diffusion.

Examples of laser light sources include, but are not limited to, diode lasers, diode-pumped solid state lasers, Er:YAG lasers, Nd:YAG lasers, argon-ion lasers, He-Ne lasers, carbon dioxide lasers, excimer lasers, ruby lasers, and so forth. For certain embodiments, a laser light source is desirably a diode laser, such as an infrared diode laser. However, it should be recognized that the selection of a particular type of laser light source in the optical delivery system **102** is dependent on the types of dermatological conditions to be treated using the dermatological apparatus **100**. The optical source **104** may include one particular type of laser light source capable of providing one wavelength or wavelength range. Alternatively, the optical source **104** may include two or more different types of laser light sources to provide a variety of different wavelengths or wavelength ranges. Optical beams from different laser light sources can be directed to the targeted portion **108** on a one-by-one basis or at the same time.

Referring to **FIG. 1**, the optical delivery system **102** also includes a focusing element **106** that is optically coupled to the optical source **104**. The focusing element **106** functions to direct optical energy from the optical source **104** to the targeted portion **108**. In the present embodiment, the focusing element **106** directs optical energy to the targeted portion **108** by focusing the power of the optical energy to one or more treatment zones within the targeted portion **108**. Desirably, multiple treatment zones are simultaneously or sequentially exposed to optical energy. Multiple treatment zones can be separated from one another so

as to form discrete treatment zones. Alternatively, or in conjunction, multiple treatment zones can intersect or overlap one another.

In the present embodiment, the focusing element **106** directs optical energy in a pattern, such as a discontinuous or microscopic pattern, so that one or more treatment zones are exposed to optical energy. Use of a pattern of optical energy provides greater efficacy of treatment by allowing for control of the fraction of the targeted portion **108** that is exposed to optical energy. Different patterns can provide a variety of different fractions of exposure, and a particular pattern can be selected based on the type of dermatological condition to be treated. For instance, in the case of a sensitive dermatological condition such as dermal melasma or deep pigmented lesions, use of a pattern of optical energy permits an effective level of treatment within multiple treatment zones. At the same time, by controlling the fraction of the targeted portion **108** that is exposed to optical energy, pain, immune system reaction, trauma, and other complications can be reduced. By having the treatment zones adjacent to healthy and substantially undamaged cells, healing of the targeted portion **108** is quicker, since the possibility of congestion or impairment of repair processes is reduced. Use of a pattern of optical energy also can facilitate multiple treatments that may be needed to produce a full desired effect by allowing an individual treatment to be milder and with lower risk to a patient. Furthermore, visible impressions of treatment can be reduced by using a pattern of treatment where an individual treatment zone is on the same or smaller scale than the normal visible texture or constituents of the skin itself.

FIG. 2, FIG. 3, and FIG. 4 illustrate various examples of patterns of optical energy that may be used to treat skin. In particular, **FIG. 2, FIG. 3, and FIG. 4** illustrate top views of targeted portions **200, 300, and 400**, respectively, to which different patterns of optical energy are directed.

Referring to **FIG. 2**, optical energy is directed to the targeted portion **200** in a “dot pattern” such that multiple treatment zones, such as treatment zones **202, 204, and 206**, within the targeted portion **200** are exposed to the optical energy. As seen from the top view of **FIG. 2**, the treatment zones are generally circular and have sizes between approximately 10 μm and 1000 μm , such as between approximately 50 μm and 500 μm . As illustrated in **FIG. 2**, the treatment zones are separated from one another and are distributed across the targeted portion **200** in a substantially regular manner, such as at intersection points of an imaginary grid. In the present example, two adjacent treatment zones, such as the treatment zones **202** and **204**, are spaced apart by a distance between approximately 30 μm and 2000

μm, such as between approximately 100 μm and 1000 μm. The fraction of the targeted portion 200 that is exposed to optical energy can be measured using a fill factor, i.e., the fraction of the area of the targeted portion 200 that is accounted for by the treatment zones as seen from the top view of FIG. 2. In general, a fill factor can be any number in the range of 0 to 1. For certain applications, a fill factor typically ranges between approximately 0.05 and 0.95, such as between approximately 0.1 and 0.5.

Depending on the particular dermatological condition to be treated, the shapes, sizes, distribution, or fill factor associated with the treatment zones may be varied from that shown in FIG. 2 by adjusting the pattern of optical energy. The treatment zones may be formed with a variety of regular or irregular shapes, such as, by way of example and not limitation, circular, half-circular, diamond-shaped, hexagonal, multi-lobal, octagonal, oval, pentagonal, rectangular, square-shaped, star-shaped, triangular, trapezoidal, wedge-shaped, and so forth. In general, the treatment zones may have the same or different shapes or sizes. The treatment zones may be distributed across the targeted region 200 uniformly or non-uniformly and at intervals that are regularly spaced or not regularly spaced. For instance, instead of the substantially regular distribution of the treatment zones shown in FIG. 2, it is contemplated that the treatment zones may be randomly distributed across the targeted portion 200. Also, it is contemplated that the treatment zones may be distributed more sparsely at or near the edges of the targeted portion 200 to produce a “feathering effect,” which reduces the visibility of the edges and produces a more uniform result when overlapping adjoining areas of treatment. This is similar to an air brush, which achieves a blended appearance with the background and adjoining brush strokes. In addition, it is contemplated that the treatment zones may be distributed across the targeted portion 200 in an arc fashion, a circular fashion, a linear fashion, a spiral fashion, or a combination thereof.

Referring next to FIG. 3, optical energy is directed to the targeted portion 300 in a “line pattern” such that multiple treatment zones, such as treatment zones 302, 304, and 306, within the targeted portion 300 are exposed to the optical energy. As seen from the top view of FIG. 3, the treatment zones are generally elongated and have widths and lengths between approximately 10 μm and 1000 μm and between approximately 1 mm and 30 mm, respectively. The treatment zones are substantially regularly spaced apart from one another, and two adjacent treatment zones, such as the treatment zones 302 and 304, are spaced apart by a distance between approximately 30 μm and 2000 μm, such as between approximately 100 μm and 1000 μm. In a similar manner as discussed above, the fraction of the targeted

portion 300 that is exposed to optical energy can be measured using a fill factor. Depending on the particular dermatological condition to be treated, the shapes, widths, lengths, distribution, or fill factor associated with the treatment zones may be varied from that shown in FIG. 3 by adjusting the pattern of optical energy. For instance, instead of the generally linear shapes of the treatment zones shown in FIG. 3, it is contemplated that one or more of the treatment zones may be shaped in an arc fashion, a circular fashion, or a spiral fashion. In general, the treatment zones may have the same or different shapes, widths, or lengths and may be distributed across the targeted portion 300 uniformly or non-uniformly and at intervals that are regularly spaced or not regularly spaced.

As illustrated in FIG. 4, optical energy is directed to the targeted portion 400 in an “intersecting line pattern” such that multiple intersecting treatment zones, such as treatment zones 402, 404, 406, and 408, within the targeted portion 400 are exposed to the optical energy. As seen from the top view of FIG. 4, the treatment zones are generally elongated and include a first set of treatment zones that intersect a second set of treatment zones at an angle. In the present example, the treatment zones may have widths, lengths, and spacings that are similar to that of the treatment zones illustrated in FIG. 3. Depending on the particular dermatological condition to be treated, the shapes, widths, lengths, distribution, or fill factor associated with the treatment zones may be varied from that shown in FIG. 4 by adjusting the pattern of optical energy. For instance, a criss-cross pattern or a honeycomb pattern of optical energy can be directed to the targeted portion 400 to vary the distribution of the treatment zones from that shown in FIG. 4.

Referring back to FIG. 1, the focusing element 106 may be implemented, at least in part, using one or more optical elements, such as mirrors, optical lenses, optical windows, and so forth, to focus the power of one or more optical beams to one or more treatment zones within the targeted portion 108. Since it is contemplated that the dermatological apparatus 100 may be used to treat a wide variety of dermatological conditions, it should be recognized that the focusing element 106 may be used to focus one or more optical beams to virtually any area or structure within the targeted portion 108, such as an epidermal layer 110 or the dermal layer 112 of the targeted portion 108.

As illustrated in FIG. 1, the dermatological apparatus 100 also includes a control system 114. The control system 114 is electronically coupled to the optical delivery system 102 via any wire or wireless transmission channel and functions to control operation of the optical delivery system 102, including the optical source 104, the focusing element 106, or

both. By way of example, the control system **114** can activate one or more laser light sources of the optical source **104** as well as control a variety of optical parameters associated with an activated laser light source. As another example, the control system **114** can control the focusing element **106** to control or adjust a pattern of optical energy that is directed to the targeted portion **108**. The focusing element **106** may be controlled by the control system **114** via, for instance, an electrical motor or any other device capable of positioning an optical element. While one optical delivery system **102** is shown coupled to the control system **114**, it is contemplated that multiple optical delivery systems may be coupled to and controlled by the control system **114**.

In the present embodiment, the control system **114** may be implemented, at least in part, using: (1) dedicated hardware or logic elements configured, for example, as a programmable gate array; (2) a typical microprocessor or central processing unit available, for example, from Intel Corp.; or (3) any typical personal computer, web appliance, or personal digital assistant product. For certain applications, the control system **114** also may include a laser driver system that interfaces with and drives the optical source **104** and a user interface to allow a user to program the control system **114**.

Referring next to **FIG. 5**, a dermatological apparatus **500** in accordance with another embodiment of the present invention is shown. The dermatological apparatus **500** includes an optical delivery system **502**, which includes an optical source **504**. The optical source **504** functions to provide optical energy that can be directed to a targeted portion **508** of a skin and may be implemented in a similar fashion as discussed for the optical source **104**.

As illustrated in **FIG. 5**, the optical delivery system **502** also includes a scanning element **516** that is coupled to the optical source **504**. The scanning element **516** functions to scan optical energy from the optical source **504** across the targeted portion **508**. In the present embodiment, the scanning element **516** is optically coupled to the optical source **504** and scans optical energy across the targeted portion **508** such that the optical energy is directed in a pattern, such as a discontinuous pattern, to one or more treatment zones within the targeted portion **508**. In particular, the scanning element **516** can scan one or more optical beams across the targeted portion **508** such that multiple treatment zones are sequentially exposed to optical energy. In the present embodiment, the scanning element **516** may be implemented, at least in part, using a scanner, such as a one-dimensional scanner or a two-dimensional scanner.

Referring to **FIG. 5**, the optical delivery system **502** further includes a focusing element **506** that is optically coupled to the scanning element **516**. The focusing element **506** functions to direct optical energy to the targeted portion **508** by focusing the power of the optical energy to one or more treatment zones within the targeted portion **508**. The focusing element **506** may be implemented in a similar fashion as discussed for the focusing element **106**. It should be recognized that the focusing element **506** may be used to focus one or more optical beams to virtually any area or structure within the targeted portion **508**, such as an epidermal layer **510** or a dermal layer **512** of the targeted portion **508**. While the scanning element **516** and the focusing element **506** are shown separate in **FIG. 5**, it is contemplated that the scanning element **516** and the focusing element **506** may be implemented in a combined fashion as a scanning/focusing element.

In the present embodiment, the optical delivery system **502** additionally includes a skin deformation element **518**, which functions to deform the targeted portion **508**. By way of example, the skin deformation element **518** can deform the targeted portion **508** in a substantially flat manner, a substantially concave manner, or a substantially convex manner. By thus deforming the targeted portion **508**, the skin deformation element **518** provides a smoother treatment surface and allows for better accuracy and control over the delivery of optical energy to the targeted portion **508**. Desirably, the skin deformation element **518** functions to apply pressure to the targeted portion **508**. The application of pressure can serve to compress the targeted portion **508** and force optically absorbing interstitial fluid away from the targeted portion **508**, thereby allowing a greater degree of penetration of optical energy into the targeted portion **508**.

In the present embodiment, the skin deformation element **518** may be implemented, at least in part, using one or more structures, such as a skin contact element, a vacuum system, or a skin stretching element, to deform the targeted portion **508**. While the focusing element **506** and the skin deformation element **518** are shown separate in **FIG. 5**, it is contemplated that the focusing element **506** and the skin deformation element **518** may be implemented in a combined fashion as a focusing/skin deformation element. For example, since the focusing element **506** forms a part of the dermatological apparatus **500**, it would reduce the number of parts in the dermatological apparatus **500** to use the focusing element **506** for focusing as well as for skin deformation.

Referring to **FIG. 5**, the dermatological apparatus **500** also includes a control system **514**. The control system **514** is electronically coupled to the optical delivery system **502** via

any wire or wireless transmission channel and functions to control operation of the optical delivery system 502, including the optical source 504, the scanning element 516, the focusing element 506, the skin deformation element 518, or a combination thereof. By way of example, the control system 514 can control the scanning element 516 to control or adjust a pattern of optical energy that is directed to the targeted portion 508. In the present embodiment, the control system 514 may be implemented in a similar fashion as discussed for the control system 114.

As illustrated in FIG. 5, the optical delivery system 502 of the present embodiment includes a sensing element 520 that functions to detect either of, or both, movement and position of the optical delivery system 502 with respect to the targeted portion 508. In particular, the sensing element 520 can provide either of, or both, movement and position data to the control system 514 to allow substantially real time control of a pattern of optical energy that is directed to the targeted portion 508. In particular, movement data provided by the sensing element 520 can allow the control system 514 to appropriately control operation of the optical delivery system 502 to account for or compensate for movement of the optical delivery system 502 with respect to the targeted portion 508. For instance, based on such movement data, the control system 514 can control the optical source 504 or the scanning element 516 to ensure integrity and substantial uniformity of the pattern of optical energy that is directed to the targeted portion 508. In the present embodiment, the sensing element 520 may be implemented, at least in part, using a movement or position detector, such as a mechanical mouse or an optical mouse.

Attention next turns to FIG. 6, which illustrates an optical delivery system 600 in accordance with an embodiment of the present invention. The optical delivery system 600 includes a housing 602 sized for manipulation by a human hand. In particular, the housing 602 is sized to allow the optical delivery system 600 to be manually scanned across a targeted portion 612 of a human skin, such as along the direction of arrow A. It should be recognized that the targeted portion 612 is illustrated in FIG. 6 in a magnified form for ease of presentation.

Located within and coupled to the housing 602 are an optical source 604 and a focusing element 606. The optical source 604 can be coupled to a control system (not shown) via a cable 616. In the present embodiment, the optical source 604 is desirably an anamorphic optical source and is implemented using a diode laser, such as an infrared diode laser. More particularly, the diode laser is desirably a linear array diode laser capable of

providing a substantially uniform optical beam that is expanded along a direction substantially orthogonal to arrow **A**, such as a direction extending out of or into the plane of **FIG. 6**. By manually scanning the optical delivery system **600** in conjunction with pulsed or intermittent application of optical energy, a “line pattern” of optical energy can be directed to the targeted portion **612**. Also, by manually rescanning the optical delivery system **600** along a direction at an angle relative to arrow **A**, an “intersecting line pattern” of optical energy can be directed to the targeted portion **612**.

While one diode laser is shown in **FIG. 6**, it is contemplated that the optical delivery system **600** may include multiple diode lasers arranged in an array, such as a one-dimensional array or a two-dimensional array. For the case of a one-dimensional array, for instance, the optical delivery system **600** can be manually scanned in conjunction with pulsed or intermittent application of optical energy such that a “dot pattern” of optical energy is directed to the targeted portion **612**. It is also contemplated that the optical delivery system **600** may include a scanning element that scans one or more optical beams from the optical source **604** across the targeted portion **612**. For the case of a one-dimensional scanner, for instance, the optical delivery system **600** can be manually scanned in conjunction with operation of the scanner such that a “dot pattern” or a “line pattern” of optical energy is directed to the targeted portion **612**. While the optical source **604** is shown located within the housing **602**, it is contemplated that the optical source **604** may be located elsewhere and may be optically coupled to the focusing element **606** via, for instance, an optical waveguide or a fiber optic cable containing one or more optical fibers.

Referring to **FIG. 6**, the focusing element **606** functions to direct optical energy from the optical source **604** to the targeted portion **612** via an optical window **622**. Desirably, a layer of a material may be applied to the targeted portion **612** for optical contact, refractive index matching, and for comfort. In the present embodiment, the focusing element **606** includes first and second optical lens **608** and **610**. Those skilled in the art will appreciate, however, that the focusing element **606** may include other optical elements (not shown) to direct optical energy to the targeted portion **612**. The first optical lens **608** functions to condition and collimate an optical beam from the optical source **604**. The first optical lens **608** may be implemented using, for instance, an aspheric optical lens with a substantially plano-convex cylindrical shape.

The second optical lens **610** functions to focus the power of the collimated optical beam to a treatment zone, such as treatment zone **614**. In the present embodiment, the

second optical lens 610 has a numerical aperture between approximately 0.15 and 1.5, such as between approximately 0.5 and 1, and may be implemented using, for instance, an optical lens with a substantially plano-convex cylindrical shape. In the present embodiment, the second optical lens 610 allows optical beams having adequate power to be focused to treatment zones within a dermal layer 620 of the targeted portion 612 while substantially avoiding damaging an epidermal layer 618 of the targeted portion 612. In particular, the optical fluence and therefore the induced temperature rise at the epidermal layer 618 can be considerably less than the optical fluence and the induced temperature rise at the focal plane deeper within the targeted portion 612, such as in the dermal layer 620. As illustrated in FIG. 6, the second optical lens 610 focuses the power of optical beams to treatment zones that are separated from one another and are relatively small or microscopic in scale along at least one dimension. Such implementation allows for greater efficacy of treatment while reducing trauma to tissue surrounding the treatment zones as well as tissue that is penetrated by the optical beams prior to reaching the treatment zones. Furthermore, such implementation reduces visible impressions of treatment because an individual treatment zone is on the same or smaller scale than the normal visible texture or constituents of the skin itself.

In the present embodiment, the treatment zones can be located up to approximately 1.5 mm below an outer surface of the skin, such as between approximately 0.15 mm and 1 mm below the outer surface. While the treatment zones are shown in the dermal layer 620 of the targeted portion 612, it is contemplated that the focusing element 606 may be used to focus optical beams to virtually any area or structure within the targeted portion 612. For instance, the focusing element 606 may be used to focus optical beams to or near the outer surface of the targeted portion 612 for a skin resurfacing treatment, such as a superficial ablative procedure. Desirably, a wavelength or range of wavelengths having high tissue absorption and low depth of penetration is used, such as between approximately 1400 nm and 14,000 nm and typically between approximately 1400 nm and 3400 nm. Tissue absorption can vary with wavelength, and, for certain applications, a wavelength or range of wavelengths is desirably chosen for which tissue absorption is highest, such as at or near 1450 nm and above 2500 nm. Skin is approximately 70 percent water, and water absorption curves can be a useful reference for locating a desirable wavelength or range of wavelengths for treatment. For certain applications, it is contemplated that two or more different wavelengths or wavelength ranges can be used, such as a first wavelength or wavelength

range having low tissue absorption and high depth of penetration and a second wavelength or wavelength range having high tissue absorption and low depth of penetration. By way of example, an optical beam having the first wavelength or wavelength range can be directed to the targeted portion 612 to achieve a pre-heating effect as well as produce coagulation of tissue down to the dermal layer 620 of the targeted portion 612, and an optical beam having the second wavelength or wavelength range can be directed to the targeted portion 612 to achieve superficial ablation of the epidermal layer 618.

For a skin resurfacing treatment, one or more holes may be formed across the outer surface of the targeted portion 612 at locations that are exposed to optical beams. Multiple holes may be formed with depths between approximately 10 μm and 1000 μm , such as between approximately 10 μm and 300 μm . For certain applications, holes are desirably formed with sizes between approximately 10 μm and 1000 μm , such as between approximately 50 μm and 500 μm . Multiple holes can be separated from one another so as to form discrete holes. Alternatively, or in conjunction, multiple holes can intersect or overlap one another. Depending on the particular treatment level and wavelength used, it is contemplated that one or more zones of thermally denatured tissue may be formed instead of, or in conjunction with, one or more holes, which denatured tissue may be subsequently sloughed off or absorbed by the body to achieve a similar skin resurfacing effect as discussed above. In particular, the desired result is the replacement of the denatured tissue by fresh tissue and the associated stimulation of new collagen and other beneficial proteins that improve the quality, appearance, and youthful character of the skin.

While not shown in FIG. 6, it is contemplated that the optical delivery system 600 may include a sensing element that can function to detect either of, or both, movement and position of the optical delivery system 600 with respect to the targeted portion 612. For instance, the sensing element may detect movement of the optical delivery system 600 as it is manually scanned across the targeted portion 612 to allow optical energy to be directed in a controlled fashion to the targeted portion 612. In particular, movement data provided by the sensing element may allow an appropriately programmed control system to alter one or more optical parameters, such as timing, to ensure integrity and substantial uniformity of the pattern of optical energy that is directed to the targeted portion 612.

Referring next to FIG. 7, an optical delivery system 700 in accordance with another embodiment of the present invention is illustrated. The optical delivery system 700 includes an optical source 704 and a focusing element 706 that is optically coupled to the optical

source 704. In the present embodiment, the optical source 704 includes multiple light sources 702A, 702B, 702C, 702D, and 702E that are arranged in an array. The light sources 702A-702E may include one particular type of laser light source or two or more different types of laser light sources. While five light sources 702A-702E are shown in FIG. 7, it is contemplated that more or less light sources can be used depending on the specific application.

In the present embodiment, the light sources 702A-702E are connected, on a one-by-one basis, to optical pathways 708A, 708B, 708C, 708D, and 708E, as illustrated in FIG. 7. For such implementation, each of the light sources 702A-702E is capable of delivering an optical beam through its own optical pathway to a targeted portion 710 of a human skin. Since the light sources 702A-702E are connected, on a one-by-one basis, to the optical pathways 708A-708E, a pattern of optical energy can be provided and delivered to the targeted portion 710. To accomplish such a pattern, a control system (not shown) can be electronically coupled to the light sources 702A-702E to select and activate one or more of the light sources 702A-702E as well as control a variety of optical parameters associated with an activated light source. In the present embodiment, the optical pathways 708A-708E are desirably optical fibers with diameters ranging from single mode fiber diameters to approximately 1 mm. However, it is contemplated that the optical pathways 708A-708E are not limited to optical fibers and, for example, could be any type of optical waveguide. It is also contemplated that optical elements, such as mirrors or optical lenses, may be employed within the context of the present embodiment to provide the functionality of the optical pathways 708A-708E.

Referring to FIG. 7, the focusing element 706 functions to focus the power of optical beams delivered via the optical pathways 708A-708E to multiple treatment zones 712A, 712B, 712C, 712D, and 712E within the targeted portion 710. In the present embodiment, the treatment zones 712A-712E desirably have sizes between approximately 10 μm and 1000 μm , such as between approximately 50 μm and 500 μm , and are separated from one another so as to form discrete treatment zones. The treatment zones 712A-712E can be located up to approximately 1.5 mm below an outer surface of the skin, such as between approximately 0.15 mm and 1 mm below the outer surface. For certain applications, different treatment zones can be located at different depths below the outer surface of the skin by, for example, arranging the optical pathways 708A-708E at different positions relative to the focusing element 706. While the treatment zones 712A-712E are shown in a

dermal layer **716** of the targeted portion **710**, it is contemplated that the focusing element **706** may be used to focus one or more optical beams to virtually any area or structure within the targeted portion **710**, such as an epidermal layer **714** of the targeted portion **710**. It is contemplated that the focusing element **706** may be used to focus optical beams to or near the outer surface of the targeted portion **710** for a skin resurfacing treatment, such as a superficial ablative procedure, in a similar manner as discussed in connection with **FIG. 6**.

While **FIG. 7** illustrates the focusing element **706** as including one optical lens, those skilled in the art will appreciate, however, that the focusing element **706** may include other optical elements (not shown) to direct optical energy to the targeted portion **710**. For instance, it is contemplated that the focusing element **706** may include two or more optical lenses. Different optical lens sizes may be used ranging, for example, from a 2-mm diameter optical lens to a 2-inch diameter optical lens. For certain applications, the focusing element **706** could be extended with individual optical elements (not shown) for each of the optical pathways **708A-708E**.

It should be recognized that the specific embodiments of the present invention discussed above are provided by way of example, and various other embodiments are encompassed by the present invention.

For instance, some embodiments of a dermatological apparatus may include a viewing system, a recording system, a displaying system, or a combination thereof. The viewing system can allow a user to view a targeted portion of a skin and may be implemented, for instance, using an observation window coupled to or included within an optical delivery system. The recording system can function to record reflected light from the targeted portion and may be implemented, for instance, using a camera or Charge Coupled Device (“CCD”) imager to record reflections in the infrared or visible spectrum. Once infrared or visible reflections are recorded, the recorded reflections can be processed by a control system and displayed as infrared or visible data using the displaying system. The displaying system may be implemented, for instance, using a computer screen, flat panel display, personal digital assistant, or wireless communication device that allows display of data.

Some embodiments of a dermatological apparatus may include a sensing element that can function to provide data to an appropriately programmed control system to allow substantially real time targeting of a pattern of optical energy to treat skin. In particular, it is contemplated that such embodiments can automatically treat skin using color or other detectable optical properties to distinguish between normal skin and skin which requires

treatment, thereby sparing normal tissue from unnecessary trauma while treating microscopically adjacent tissue which requires treatment. The sensing element may be implemented, for instance, using color-discriminating detectors as described in U.S. Patent No. 5,531,740 to Black, entitled "Automatic Color-Activated Scanning Treatment of Dermatological Conditions by Laser," the disclosure of which is incorporated herein by reference in its entirety.

As another example, some embodiments of a dermatological apparatus may include a cooling system. The cooling system can function to dynamically or statically control the temperature of a targeted portion of a skin prior to, during, or after treatment and may be implemented, for instance, using a fluid delivery apparatus or a cold skin contact element.

As a yet another example, some embodiments of the present invention relate to the treatment of a wide variety of biological tissues using patterns of optical energy. In particular biological tissues that have an epithelial protective layer corresponding to an epidermal layer of skin also may be treated in a similar manner as discussed herein. For instance, patterns of optical energy may be applied to the soft palate for treatment of snoring and sleep apnea.

The following example describes specific aspects of the present invention to illustrate and provide a description of the present invention for those of ordinary skill in the art. The example should not be construed as limiting the present invention, as the example merely provides specific methodology useful in understanding and practicing the present invention.

EXAMPLE

In vitro skin (sample size = 4 mm x 6 mm) was placed next to a glass plate with an anti-reflective coating and compressed slightly with a small weight. Optical energy (wavelength = 1500 nm; pulse duration = 10 ms; and pulse power = 1000 mW) from a laser light source was delivered using an optical fiber and then focused through the glass plate and within the skin using a beam collimator and a focusing objective (numerical aperture = 0.53). The depth of a treatment zone that was exposed to optical energy could be varied between approximately 500 μ m to 700 μ m below an outer surface of the skin by adjusting the distance between the focusing objective and the glass plate. A transparent lotion was used as an index matching material between the glass plate and the skin. This lotion also helped keep the skin moist and improved conduction of excess thermal energy away from a treatment zone. A single laser pulse was directed to each treatment zone, and, in this

fashion, various treatment zones within the skin were exposed to optical energy. The treatment zones were distributed at intersection points of a rectangular grid and were spaced apart by a distance of approximately 500 μm . The treatment zones were generally elongated and had widths of approximately 200 μm .

5 The present invention has now been described in accordance with several exemplary embodiments, which are intended to be illustrative in all aspects, rather than restrictive. Thus, the present invention is capable of many variations in detailed implementation, which may be derived from the description contained herein by a person of ordinary skill in the art. All such variations are considered to be within the scope and spirit of the present invention
10 as defined by the following claims and their legal equivalents.

WHAT IS CLAIMED IS:

1. A dermatological apparatus comprising:

a plurality of light source and optical pathway connections, wherein each light source in said plurality of light source and optical pathway connections is capable of delivering an optical beam through its connected optical pathway to a targeted portion of a human skin;

a control system to select and control said light sources to deliver a plurality of optical beams in a discontinuous pattern; and

a focusing element to focus the power of said delivered optical beams to a plurality of discrete treatment zones that are located up to 1.5 mm underneath an outer surface of said targeted portion, said discrete treatment zones having sizes in the range of 10 μm to 1000 μm .

2. The dermatological apparatus of claim 1, wherein said discrete treatment zones have sizes in the range of 50 μm to 500 μm .

3. The dermatological apparatus of claim 1, wherein said discrete treatment zones are located in a dermal layer of said targeted portion.

4. The dermatological apparatus of claim 3, wherein said focusing element focuses the power of said delivered optical beams to said discrete treatment zones while substantially avoiding damaging an epidermal layer of said targeted portion.

5. A dermatological apparatus comprising:

a plurality of light source and optical pathway connections, wherein each light source in said plurality of light source and optical pathway connections is capable of delivering an optical beam through its connected optical pathway to an outer portion of a human skin;

a control system to select and control said light sources to deliver a plurality of optical beams in a discontinuous pattern; and

a focusing element to focus the power of said delivered optical beams to said outer portion to form a plurality of discrete holes distributed across said outer portion, said discrete holes having sizes in the range of 10 μm to 1000 μm .

6. The dermatological apparatus of claim 5, wherein said discrete holes have sizes in the range of 50 μm to 500 μm .

7. The dermatological apparatus of claim 5, wherein said discrete holes have depths in
5 the range of 10 μm to 1000 μm .

8. The dermatological apparatus of claim 5, wherein said discrete holes are distributed across said outer portion with a fill factor in the range of 0.1 to 0.5.

10 9. A dermatological apparatus comprising:

an optical delivery system, said optical delivery system including

an optical source, said optical source being configured to provide optical energy having a wavelength in the range of 400 nm to 20,000 nm; and

a focusing element optically coupled to said optical source, said focusing
15 element being configured to direct said optical energy in a discontinuous pattern to a targeted portion of a skin.

10. The dermatological apparatus of claim 9, wherein said optical delivery system further includes a housing sized for manipulation by a human hand, said optical source and said
20 focusing element being located within said housing.

11. The dermatological apparatus of claim 9, wherein said optical source includes a plurality of laser light sources.

25 12. The dermatological apparatus of claim 9, wherein said focusing element is configured to direct said optical energy in said discontinuous pattern to said targeted portion such that a plurality of discrete treatment zones within said targeted portion are exposed to said optical energy.

30 13. The dermatological apparatus of claim 12, wherein said discrete treatment zones have sizes in the range of 10 μm to 1000 μm .

14. The dermatological apparatus of claim 12, wherein said discrete treatment zones are located in at least one of an epidermal layer and a dermal layer of said targeted portion.

15. The dermatological apparatus of claim 9, wherein said focusing element is configured to direct said optical energy to said targeted portion in one of a dot pattern and a line pattern.

16. The dermatological apparatus of claim 9, wherein said focusing element is configured to direct said optical energy to said targeted portion in the form of a plurality of optical beams.

17. The dermatological apparatus of claim 9, wherein said optical delivery system further includes a scanning element optically coupled to said optical source and to said focusing element, said scanning element being configured to scan said optical energy across said targeted portion.

18. A dermatological apparatus comprising:

an optical delivery system, said optical delivery system including

an optical source; and

a focusing element optically coupled to said optical source, said focusing element being configured to direct optical energy from said optical source to a targeted portion of a skin, said focusing element including an optical lens having a numerical aperture in the range of 0.15 to 1.5, said optical lens being configured to focus said optical energy to a dermal layer of said targeted portion.

19. The dermatological apparatus of claim 18, further comprising:

a control system electronically coupled to said optical delivery system, said control system being configured to control said optical delivery system.

20. The dermatological apparatus of claim 18, wherein said optical source includes at least one laser light source.

21. The dermatological apparatus of claim 18, wherein said optical source is configured to provide said optical energy having a wavelength in the range of 400 nm to 20,000 nm.

22. The dermatological apparatus of claim 18, wherein said optical lens is configured to focus said optical energy to a treatment zone within said dermal layer of said targeted portion while substantially avoiding damaging an epidermal layer of said targeted portion.

5 23. The dermatological apparatus of claim 22, wherein said treatment zone has a size in the range of 10 μm to 1000 μm .

24. The dermatological apparatus of claim 22, wherein said treatment zone is located in the range of 0.15 mm to 1 mm underneath an outer surface of said targeted portion.

10 25. The dermatological apparatus of claim 22, wherein said treatment zone is substantially circular.

26. The dermatological apparatus of claim 22, wherein said treatment zone is elongated.

15 27. A dermatological apparatus comprising:
a housing sized for manipulation by a human hand;
an optical source located within said housing, said optical source being configured to provide optical energy; and

20 a focusing element coupled to said housing, said focusing element being configured to direct said optical energy to a targeted portion of a skin such that a plurality of treatment zones within said targeted portion are exposed to said optical energy, said treatment zones being separated from one another within said targeted portion.

25 28. The dermatological apparatus of claim 27, further comprising:
a control system electronically coupled to said optical source, said control system being configured to control said optical source to provide said optical energy.

29. The dermatological apparatus of claim 27, further comprising:
30 a skin deformation element coupled to said housing, said skin deformation element being configured to deform said targeted portion.

30. The dermatological apparatus of claim 27, wherein said optical source is configured to provide said optical energy having a wavelength in the range of 600 nm to 4000 nm.

5 31. The dermatological apparatus of claim 27, wherein said optical source includes at least one diode laser.

32. The dermatological apparatus of claim 27, wherein said focusing element is configured to direct said optical energy to said targeted portion such that said treatment zones are substantially simultaneously exposed to said optical energy.

10

33. The dermatological apparatus of claim 27, wherein said focusing element is configured to direct said optical energy to said targeted portion such that said treatment zones are sequentially exposed to said optical energy.

15

34. The dermatological apparatus of claim 27, wherein said focusing element includes at least one optical lens, said optical lens being configured to focus said optical energy up to 1.5 mm underneath an outer surface of said targeted portion.

20

35. The dermatological apparatus of claim 27, wherein said focusing element includes at least one cylindrical lens having a numerical aperture in the range of 0.15 to 1.5.

36. The dermatological apparatus of claim 27, wherein said treatment zones are distributed substantially uniformly across said targeted portion.

25

37. The dermatological apparatus of claim 27, wherein said treatment zones have sizes in the range of 50 μm to 500 μm .

38. A dermatological apparatus comprising:

30

an optical delivery system, said optical delivery system being configured to direct optical energy in a pattern to a targeted portion of a skin such that a plurality of discrete treatment zones within said targeted portion are exposed to said optical energy, said discrete treatment zones having sizes in the range of 10 μm to 1000 μm .

39. The dermatological apparatus of claim 38, wherein said optical delivery system includes a focusing element, said focusing element being configured to direct said optical energy up to 1.5 mm underneath an outer surface of said targeted portion.

5 40. The dermatological apparatus of claim 39, wherein said optical delivery system further includes an optical source optically coupled to said focusing element, said optical source being configured to provide said optical energy having a wavelength in the range of 400 nm to 20,000 nm.

10 41. A method of treating a human skin, comprising:
providing optical energy, said optical energy having optical parameters to produce a dermatological effect for a targeted portion of said human skin; and
directing said optical energy to said targeted portion such that a plurality of discrete treatment zones within said targeted portion are substantially simultaneously exposed to said
15 optical energy.

42. The method of claim 41, wherein two adjacent discrete treatment zones of said plurality of discrete treatment zones are separated by a distance in the range of 100 μm to 1000 μm .

20 43. The method of claim 41, wherein directing said optical energy to said targeted portion includes focusing said optical energy to a dermal layer of said targeted portion while substantially avoiding damaging an epidermal layer of said targeted portion.

25 44. A method of treating a human skin, comprising:
providing optical energy; and
directing said optical energy to an outer portion of said human skin to form a plurality of discrete holes distributed across said outer portion, said discrete holes having sizes in the range of 10 μm to 1000 μm .

30 45. The method of claim 44, wherein said optical energy has a wavelength in the range of 1400 nm to 14,000 nm.

46. The method of claim 44, wherein said discrete holes have depths in the range of 10 μm to 1000 μm .

5 47. The method of claim 44, wherein said discrete holes are distributed across said outer portion with a fill factor in the range of 0.05 to 0.95.

48. The method of claim 44, wherein said discrete holes are distributed across said outer portion with a fill factor in the range of 0.1 to 0.5.

10 49. The method of claim 44, wherein directing said optical energy to said outer portion includes scanning said optical energy across said outer portion.

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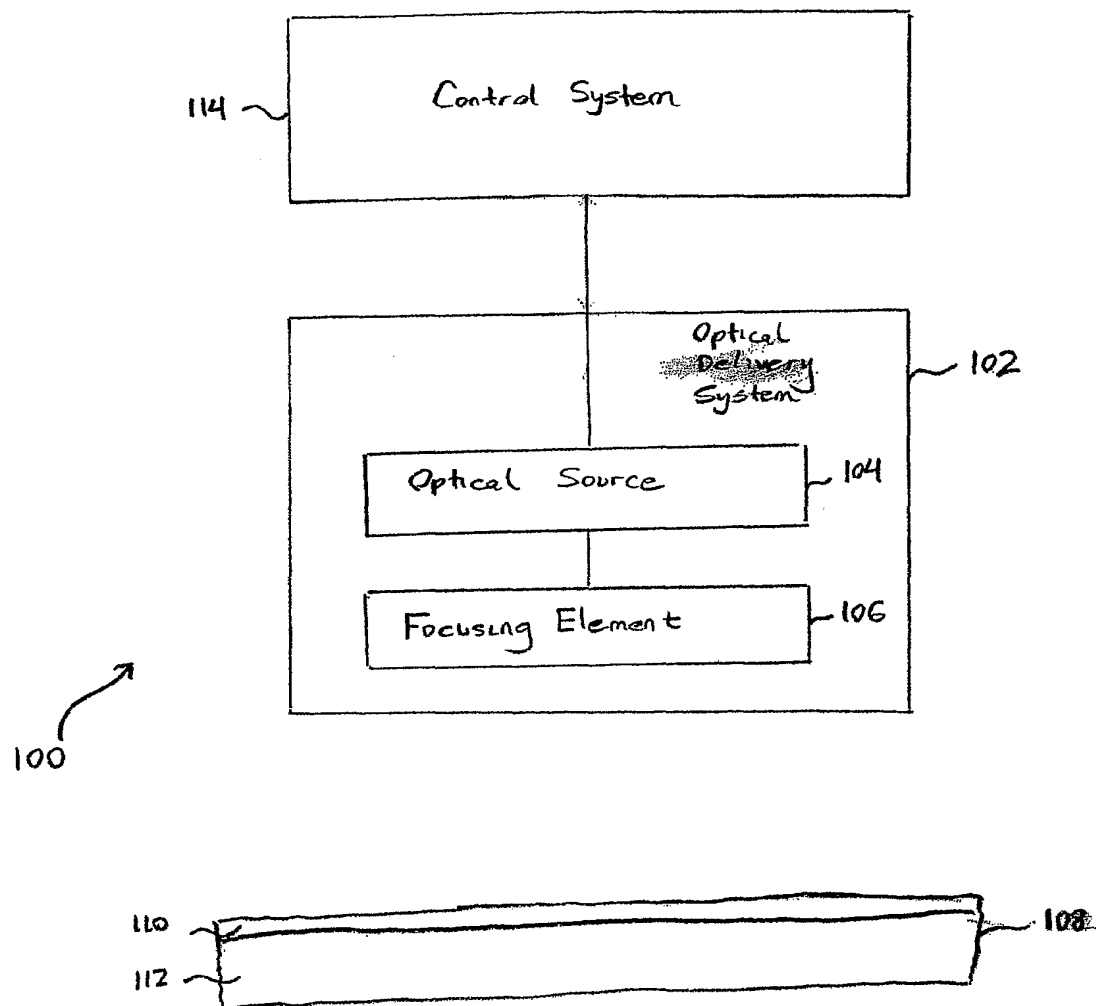


FIG. 1

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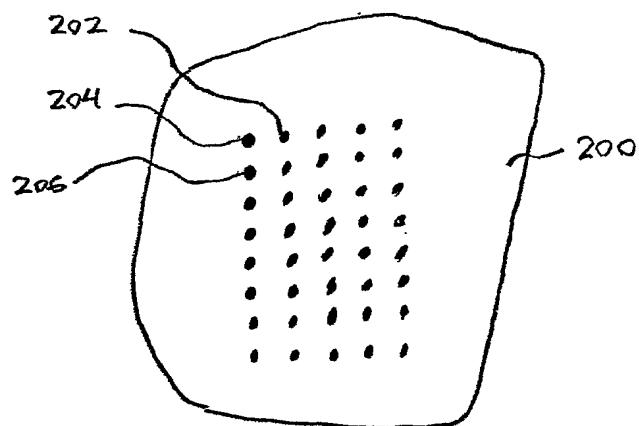


FIG. 2

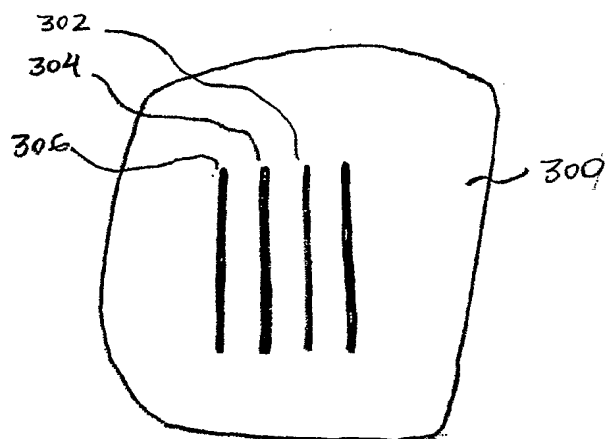


FIG. 3

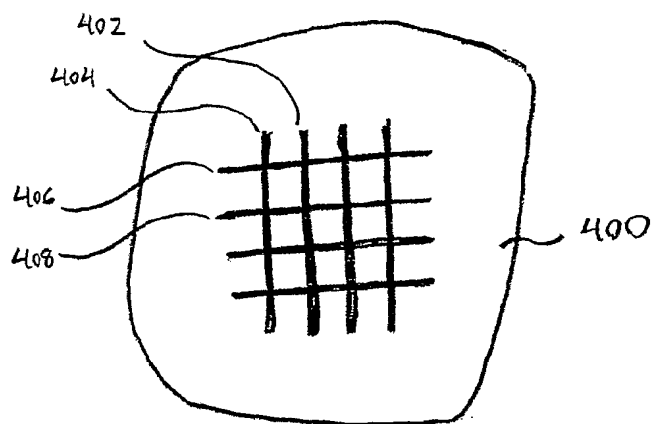


FIG. 4

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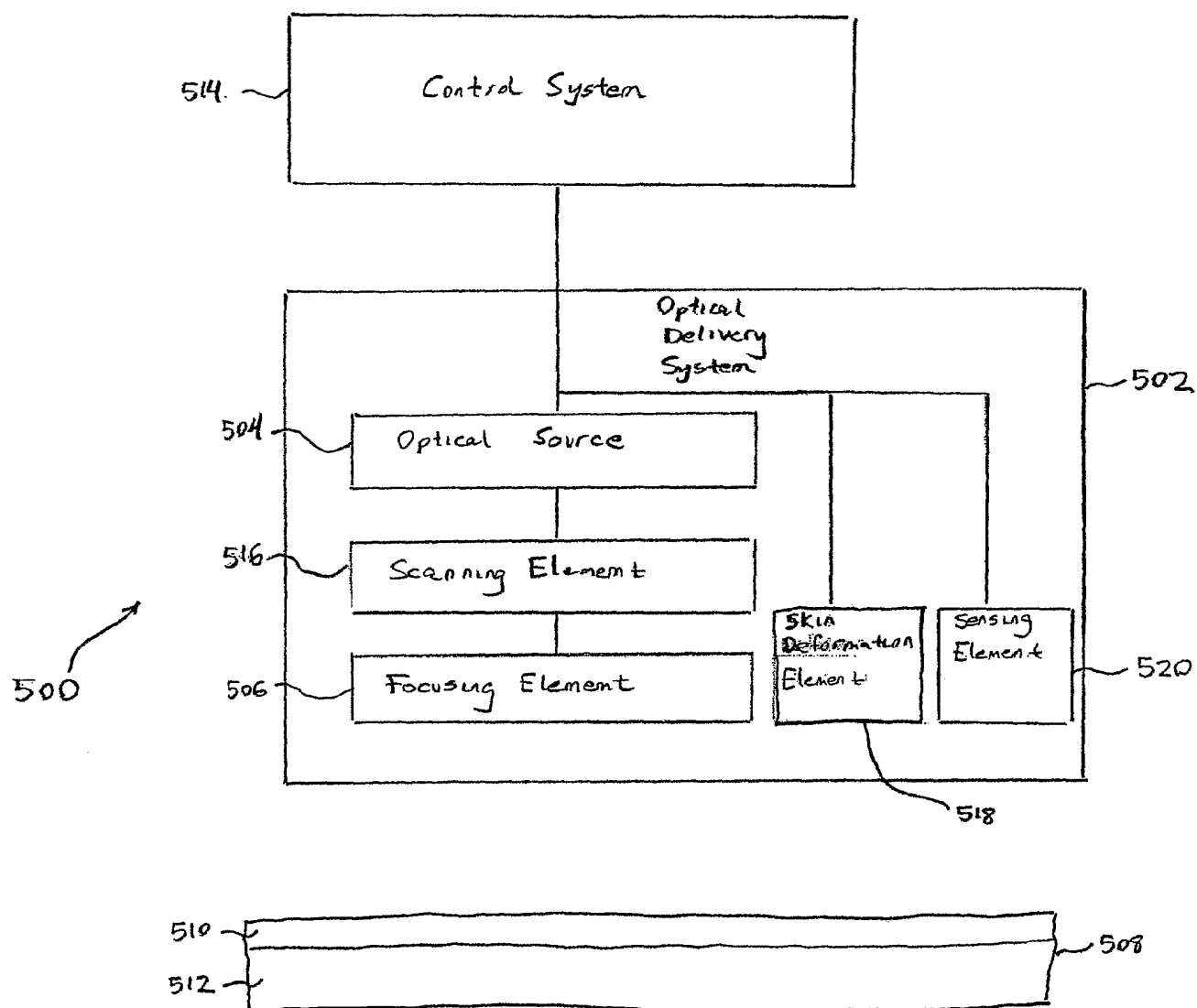


FIG. 5

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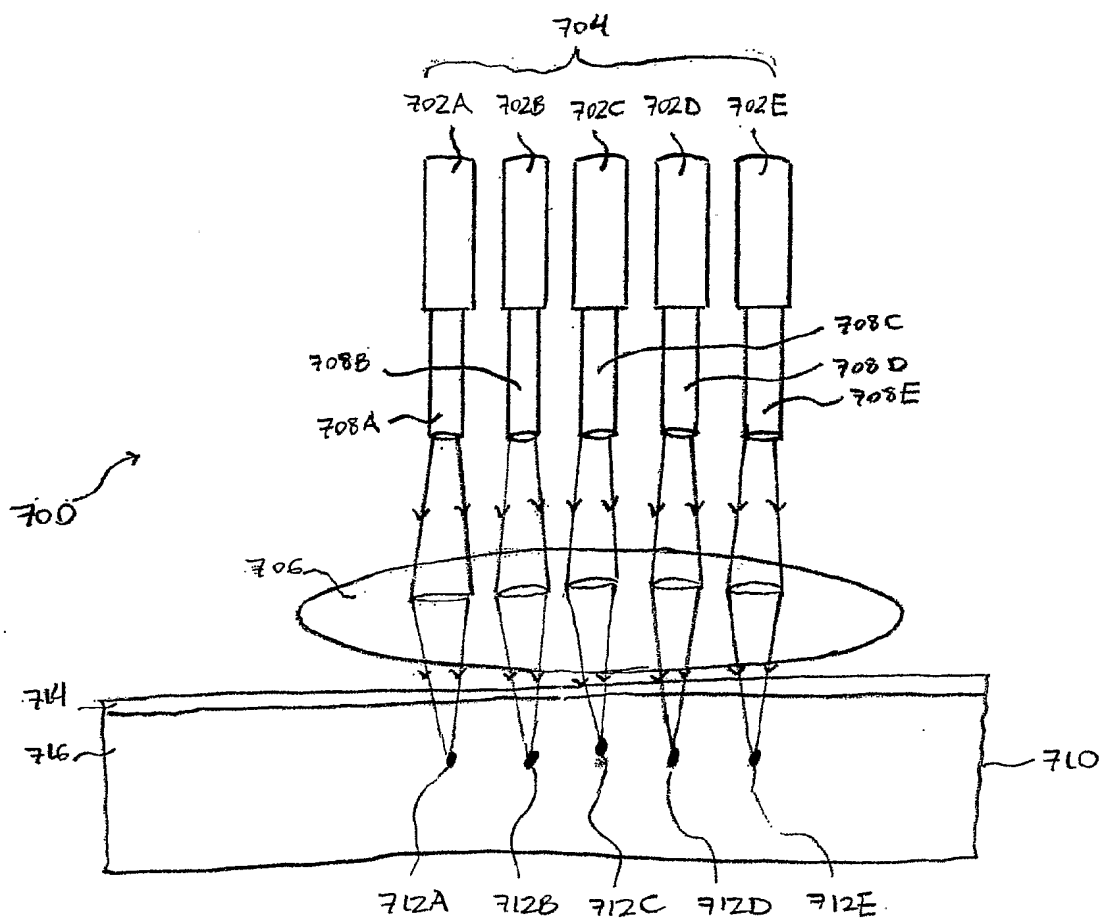


FIG. 7

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(71) Applicant: **PALOMAR MEDICAL TECHNOLOGIES, INC.** [US/US]; 82 Cambridge Street, Burlington, MA 01803 (US).

(72) Inventors: **ALTSHULER, Gregory, B.**; 137 Marion Street, Wilmington, MA 01887 (US). **YAROSLAVSKY, Ilya**; 9214 Avalon Drive, Wilmington, MA 01887 (US). **BURKE, James, III**; 2 Angus Avenue, Londonderry, NH 03053 (US). **EROFEEV, Andrei, V.**; 38 Royal Crest Drive, Suite 7, North Andover, MA 01845 (US). **ZENZIE, Henry, H.**; 14 Whiting Road, Dover, MA 02030 (US). **LOPEZ, Robert, R.**; 38 Belvedere Road, Boxford, MA 01921 (US). **GAAL, Christopher**; 25 Longwood Circle, Mansfield, MA 02048 (US).

(74) Agents: **ENGELLENER, Thomas J.** et al.; Nutter McClennen & Fish LLP, World Trade Center West, 155 Seaport Boulevard, Boston, MA 02210-2604 (US).

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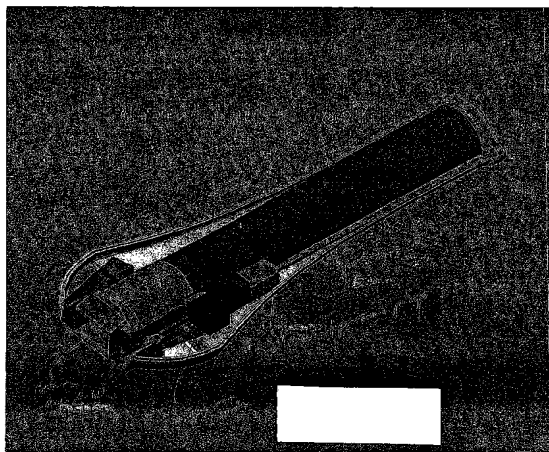
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(54) Title: **PHOTOTREATMENT DEVICE FOR USE WITH COOLANTS AND TOPICAL SUBSTANCES**



(57) **Abstract:** Methods and systems are disclosed for phototreatment in which replaceable containers comprising one or more adjuvant (consumable or re-useable) substances are employed. The adjuvant substance can be, for example, a topical substance or a coolant. Systems are disclosed for using a topical substance to detect contact of a phototreatment device with a tissue, detect speed of a phototreatment device over the tissue, detect regions of tissue that have been treated by a phototreatment device and/or to provide other benefits to the tissue such as improved skin tone and texture, tanning, etc. Safety systems are also disclosed that ensure that a proper consumable substance and/or container is connected to a phototreatment device and/or directed to a proper target. Additionally, cooling systems and methods that utilize phase change materials for extracting heat from a light generating device are disclosed.

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**PHOTOTREATMENT DEVICE FOR USE WITH COOLANTS
AND TOPICAL SUBSTANCES**

PRIORITY

This application is a continuation-in-part of U.S. application No. 10/154,756 filed May 23, 2002 and claims priority to U.S. provisional application No. 60/420,645 filed October 23, 2002 and U.S. provisional application No. 60/498,258 filed August 25, 2003.

BACKGROUND OF THE INVENTION

The present invention is directed generally to systems and methods for phototreatment in which adjuvant substances are used for cooling or topical applications.

There exists a variety of conditions that are treatable using phototreatments of tissue (e.g., phototherapeutic and photocosmetic treatments). Such phototreatments include light-based hair removal, treatment of various skin lesions (including pigmented and vascular lesions as well as acne), tattoo removal, facial skin improvement, fat and cellulite treatment, scar removal, and skin rejuvenation (including wrinkle reduction and improvement of tone and texture), odor reduction, acne treatment to name a few.

Typically, light from a phototreatment device treats a tissue using a photothermal mechanism (i.e., a target structure or a tissue proximate the target structure is heated to effect the treatment) and/or a photodynamic therapy mechanism (i.e., the light causes a photochemical reaction). A variety of different light sources can be incorporated into a handpiece of a photocosmetic device for generating radiation suitable for a desired treatment of a patient's skin. These light sources, which can be either coherent or non-coherent, can emit light at a single wavelength, multiple wavelengths or in one or more wavelength bands. Some examples of such light sources include, without limitation, diode lasers, LEDs, arc lamps, flash lamps, tungsten lamps, and any other suitable light emitting devices.

Such light sources typically convert a portion of an applied electrical energy into optical energy while the rest of the electrical energy is converted into waste heat. For example, in a photocosmetic device that utilizes a diode laser bar as the source of optical radiation, up to about 40 - 60% of the electrical energy may be converted into waste

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heat. For LEDs, this loss can be as high as 70-99%. Other light sources may exhibit different efficiencies for generating optical energy. However, in general, a substantial amount of waste heat is generated that needs to be removed in order to ensure proper operation of the light source and to prevent shortening its lifetime. In addition, heat removal is important to ensure that the temperature of the components of the handpiece that are in contact with a patient's skin remain in a suitable range that is not damaging to the skin.

Adjuvant substances include consumable and reusable coolants to be applied to one or more target components of a phototreatment device. For example, because of the use of high-power radiation to perform phototreatments, one or more electronic or optical components may generate significant amounts of heat. Such components include, for example, laser diodes, LED or high-power electrical components. Coolants for removing heat from such components have been used to reduce the expense of maintaining phototreatment devices by increasing their operational lifetimes and/or to improve their safety.

Phototreatment devices are also often used with other consumable materials including, for example, topical substances. Conventional topical substances include any suitable topical liquid or emollient, such as a lotion, gel, water, alcohol, or oil. Such topical substances may be used, for example, to improve the safety of a device, efficacy of a treatment, cosmetic qualities of a treated tissue, and/or comfort of a patient.

While consumable substances, such as those discussed above may provide benefits, the use of consumable materials may lead to difficulty and expense in packaging, handling, and manufacturing of phototreatment devices employing such materials. Hence, there is a need for methods and systems that allow efficient and cost effective delivery of adjuvant substances during phototreatment.

SUMMARY OF THE INVENTION

Methods and systems are disclosed for phototreatment in which replaceable containers comprising one or more adjuvant (consumable or re-useable) substances are employed. The adjuvant substance can be, for example, a topical substance or a coolant. Systems are disclosed for using a topical substance to detect contact of a phototreatment device with a tissue, detect speed of a phototreatment device over the tissue, detect

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regions of tissue that have been treated by a phototreatment device and/or to provide other benefits to the tissue such as improved skin tone and texture, tanning, etc. Safety systems are also disclosed that ensure that a proper consumable substance and/or
5 container is connected to a phototreatment device and/or directed to a proper target. Additionally, cooling systems and methods that utilize phase change materials for extracting heat from a light generating device are disclosed.

In one aspect, the invention provides a container having a container housing defining at least one compartment therein, a substance contained in the compartment,
10 and an indicator coupled to the compartment for monitoring substance release during phototreatment. The housing and compartment are capable of being coupled to a phototreatment device to provide a flow path for substance release during phototreatment. The compartment can be fluidly coupled to at least one element selected from the group consisting of a head of a phototreatment device, a heat
15 dissipating element in the phototreatment device, a target area, and a tissue region to be treated. The indicator can indicate an aspect of the container (i.e., amount of substance contained therein, temperature, etc.) or the substance (i.e., temperature, activity, etc.). The indicator can be selected, for example, from the group including mechanical indicia, optical indicia, magnetic indicia, electronic indicia, and piezoelectronic indicia. The
20 substance can be a consumable substance and can contain a marker.

In another aspect of the invention, a subassembly is disclosed for use with a phototreatment device to treat a tissue. The subassembly has a container capable of storing a substance and coupling to the phototreatment device. The subassembly can further include a detector coupled to the container and configured and arranged to
25 monitor a substance parameter. The container can have an outlet to allow release and/or replenishing of the substance, which can be a consumable substance, such as a coolant and a topical substance. Non-limiting examples of a topical substance include lotions, water, alcohols, oils, gels, powders, aerosols, granular particles, creams, gels, waxes, and films. The consumable substance can include a super-cooled liquid, a pressurized gas,
30 or a phase change material. For example, the consumable substance can be a phase-changing material exhibiting a phase transition from a liquid to a gaseous state or exhibiting a phase transition from a solid to a liquid state. Suitable phase change materials include, but are not limited to, liquid carbon tetrafluoride, liquid CO₂, ice,

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frozen lotions, frozen wax, frozen creams and frozen gels. The container can be fluidly coupled to the device, a tissue region, a target area, a head of the device, or a heat dissipating element located within the device, e.g., located in a handle of the device.

5 The container can also contain a reusable substance, such as a phase-change material. The detector can be a mechanical detector, an optical detector, a magnetic detector, an electronic detector, and a piezoelectronic detector. The subassembly can be replaced by the user.

10 In another aspect, the invention discloses a container having a housing defining at least one compartment therein, a substance contained in the compartment. The housing and the compartment are capable of coupling to a phototreatment device to permit heat transfer between the substance and the device. The container further includes an indicator coupled to the compartment. The compartment is capable of being fluidly coupled to at least one of a head of a phototreatment device, a heat dissipating
15 element, or a tissue to be treated. The substance contained in the container can be a re-useable substance, such as a phase change material, or a consumable substance, such as a coolant or topical substance. The substance can further contain a marker. Non-limiting examples of markers include absorptive markers, photoactive markers, optical markers, fluorescent markers, electric markers, and magnetic markers. The marker can
20 indicate an aspect of the substance. The marker can be selected from the group consisting of dyes, metals, ions, colored particles, photosensitive dyes, photosensitive materials, carbon particles, conductive skin lotions, electrolyte sprays, conductive electrode gels, and oxides.

25 At least one compartment of the container can have a first compartment and a second compartment, the first compartment is adapted to couple to a tissue, and the second compartment is adapted to couple to a heat dissipating element in the phototreatment device. The first compartment can contain a topical substance, such as lotion, cream, wax, film, water, alcohol, oil, gel, powder, aerosol, and granular particles. The topical substance can achieve at least one of moisturizing skin, UV protection,
30 tanning skin, improving skin texture, improving skin tone, reduction and/or prevention of cellulite, reduction and/or prevention of acne, wrinkle reduction and/or prevention of wrinkles, reduction of scars, reduction and/or prevention of vascular lesions, reduction in pore size, oil reduction in sebum secretion, skin elasticity improvement, reduction in

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sweat secretion, reduction and/or improvement of odor, body hair reduction or removal, and stimulation of hair growth. The second compartment of the container can contain a coolant. Non-limiting examples of a coolant include liquid tetrafluorethane (R-134a),
5 liquid CO₂, ice, frozen lotion, frozen gel, cristallohydrates (45%CaCl*6H₂O:
55%CaBr*6H₂O ore KF*4H₂O), organic materials as HO(C₂H₄O)₈C₂H₄OH (PE Glycol), Caprilic acid, Hexadecane, and Paraffin 5913. A single consumable substance can function as a topical substance and a coolant, and can be directed to both tissue and a heat dissipating element. In some embodiments of the present invention, a container
10 for a topical substance and/or coolant comprises a first compartment fluidly connectable to a tissue, and a second compartment fluidly connectable to a heat dissipating element of the phototreatment device.

In another aspect, the invention provides a method of operating a phototreatment device comprising the steps of coupling a container of an adjuvant substance, having an
15 indicator associated therewith to permit monitoring of the substance, to a phototreatment device, determining a value of the indicator, and enabling operation of the phototreatment device if the value is acceptable. The step of enabling operation can include, for example, activating a radiation source. The indicator can be, without limitation, an optical indicator, mechanical indicator, electronic indicator, and magnetic
20 indicator.

In yet another aspect, the invention provides a system, having a radiation source, a detector, and a processor, for measuring a speed of motion of a phototreatment device over a tissue region, where the phototreatment device has an electromagnetic source to effect a phototreatment and the tissue region has a substance applied thereto. An
25 applicator coupled to the phototreatment device can be used for depositing the substance, which can contain a marker, onto the tissue prior to irradiation of the tissue region by the radiation source. The substance contains a marker. Non-limiting examples of markers include fluorescent markers, absorptive markers, electrical markers, optical markers, and magnetic markers. The radiation source can be positioned
30 on the phototreatment device to irradiate the tissue region and the applied substance. The detector is associated with the phototherapeutic device configured and arranged to monitor the substance. The processor calculates a speed of motion of the phototreatment device based on signals from the detector. The radiation source can be further coupled

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to the phototreatment device for irradiating a plurality of tissue locations and the substance applied thereto as the device moves over the tissue region. The detector can be further coupled to the phototreatment device at a selected distance from the radiation source and arranged to monitor a response of the substance at an irradiated location subsequent to the irradiation. The processor can be further coupled to the detector for comparing the monitored response with a pre-selected value to determine a continuous or discrete speed of motion of the phototreatment device.

The system can contain a comparator for comparing the calculated speed of motion with a defined maximum speed value in order to determine when the calculated speed has exceeded a threshold established by the defined maximum speed. A maximum speed can be in the 10-500 mm/sec range. A comparator can also be used for comparing the calculated speed of motion with a defined minimum speed value in order to determine when the calculated speed has fallen below a threshold established by the defined minimum speed. A minimum speed can be in the 5-100 mm/sec range. The system also contains a shut-off switch responsive to a control signal to terminate phototreatment when the speed has fallen below the threshold, thereby preventing potential injury to the user, or when the speed is above the threshold, thereby preventing ineffective treatment. For example, the control signal can enable the processor to control the electromagnetic source based on the speed of the phototherapeutic device. The shut-off switch can include a shutter that blocks the radiation and/or an alarm to alert the user.

In another aspect, the invention provides a method of operating a phototreatment device that includes the steps of applying a topical substance to a tissue, detecting a parameter associated with the topical substance, and enabling operation of the phototreatment device based on a detected value of the substance parameter.

In yet another aspect, a phototreatment device for use with a marker is disclosed. The device includes a radiation source to effect a phototreatment on a region of tissue, and a detector assembly to detect the marker and to selectively activate the radiation source based on marker detection. The detector can be, for example, an optical detector, a heat detector, an electronic detector, a mechanical detector, or a magnetic detector. The detector assembly can be configured and arranged to detect a reflected portion of light from an object, and to determine if the object is a tissue. The device can also have

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an applicator configured and arranged to deposit the marker in at least a portion of the region.

5 In other aspects, applicants have realized that a phase transition of a phase change material can be employed to extract heat from an element that is heated or generates heat ("heated element") and is incorporated in a handpiece of a photocosmetic device. The heated element may be any element that generates heat. Such heat generating elements can include, for example, a light source, a portion of a patient's skin or electronics incorporated in the device. Further, a heated element can include any
10 element that receives heat (i.e., it is heated) from a heat generating source. Such elements can include, for example, a heat sink, a heat exchanger, a heat spreader, a heat pipe, a heat transfer element, a circulating gas or liquid, or components (including optical components) that are in thermal contact with a treatment site. The term "phase change material," as used herein, refers to any substance or compound that exhibits at
15 least two phases between which a transition can be caused by either removing heat from or depositing heat into the substance or compound. The transition between these phases typically occurs at a well defined temperature herein referred to as a phase transition temperature, which can depend on ambient pressure. The heat deposited or removed from such a phase transition material at the phase transition temperature is herein
20 referred to as the latent heat associated with the phase transition. For example, a phase change material can be initially in a solid phase, and can transition into a liquid phase by absorbing an amount of heat, which is herein referred to as the latent heat of melting.

In many embodiments of the invention described below, ice is employed as a phase change material for removing waste heat generated by a light source incorporated
25 in a handpiece of a photocosmetic device. Applicants have discovered that ice is a particularly suitable material for use in various embodiments of the invention because it exhibits a fairly high latent heat of melting, namely, 330 J/g at atmospheric pressure, thus providing an efficient mechanism for heat removal. Further, melting of ice generates water, which is a biologically compatible substance, is environmentally safe, and can be mixed with skin beneficial compounds. Although ice is described below as
30 one preferred substance whose phase transition can be utilized in the practice of the invention for heat removal, it should be understood that other suitable phase transition materials can also be employed. Further, rather than utilizing the latent heat of melting,

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the latent heat of sublimation of a phase transition material, such as dry ice, can be utilized in the practice of the invention to remove heat from a heated element.

5 A variety of different embodiments that utilize such phase change for cooling a photocosmetic device are described below. In principle, the phase change medium, e.g., ice, can be provided in the handpiece itself to be in thermal contact with a heat generator (e.g., a light source), typically via a heat transfer element (e.g., a copper block), or in thermal contact with any other heated element. Alternatively, the phase transition medium can be provided in a base of the photocosmetic device to extract heat from a
10 cooling fluid that circulates between the base and the handpiece to cool a heat generator (e.g., light source) or any other heated element (e.g., the optical system that delivers light onto a patient's skin). Those having ordinary skill in the art will appreciate that other alternative approaches are also possible. For example, phase transition media can be provided both in the handpiece for direct cooling of the heated elements in the
15 handpiece (e.g., the skin and/or light source) and in the base for functioning as a heat exchanger for electronics.

In one aspect, the invention provides a closed-loop (renewable) cooling system for extracting heat from a heated element of a photocosmetic device in which a phase change medium, e.g., ice, subsequent to its phase transition as a result of heat absorption
20 is regenerated in a state suitable for heat extraction, and is reused. The regeneration of the phase change medium can be performed, for example, by a refrigeration unit incorporated in, or externally coupled to the photocosmetic device.

In another aspect, a phase change medium is utilized to extract heat from a circulating fluid that in turn removes heat from a heated element of a photocosmetic
25 device. The phase change medium can be located remotely relative to the heated element.

The term "thermal contact" is generally known in the art. To the extent that a definition may be needed, this term as used herein is intended to encompass any coupling between at least two elements that allows transfer of heat between them. Such
30 a thermal coupling can be obtained by a direct physical contact between the elements, or via an intermediate heat conducting element, or heat pipe or loop with circulating gas or liquid. A heat exchanger is a device for transferring heat from one medium to another, for example, from water to air, from ice to water, or from water to water. The better the

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thermal contact between the media, the more effective the heat exchanger.

Alternatively, or in addition, radiative heat transfer can be established between two elements without direct physical contact or the use of an intermediate heat conducting element. Hence, in general, two elements are in thermal contact so long as heat can be transferred between them.

In further aspects, the invention provides a cartridge that can contain a selected quantity of a phase change material. The cartridge can couple to a heated element incorporated in a photocosmetic device, so as to bring the phase change material into thermal contact therewith. The heat transfer from the heated element to the phase change medium causes a phase transition of the phase change medium, for example, from a solid state to a liquid state, thereby removing heat from the heated element. The cartridge can further include a flow path for directing fluid, which can be generated following the phase change, away from the heated element.

In another aspect, the invention provides a cartridge for storing a phase change medium, which can be removably and replaceably placed within the flow path of a cooling fluid utilized for extracting heat from a heated element of a photocosmetic device. A phase transition of the phase change medium removes heat carried by the cooling fluid, thereby lowering its temperature.

In another aspect, the invention provides mechanisms for applying pressure to a phase change medium to facilitate maintaining good or optimum thermal contact between the phase change medium and a heated element incorporated in a photocosmetic device. The applied pressure ensures that the phase change medium remains in good or optimum thermal contact with the heated element as the heat from the heated element causes a phase transition of the phase change medium at its interface with the heated element.

In yet another aspect, the invention provides a cooling device, in which a phase change medium can be stored, that can couple to an optically transmissive element of a handpiece of a photocosmetic device so as to provide thermal contact between the phase change medium and the optical element. A phase transition of the phase change medium extracts heat from the optical element, thereby maintaining its temperature in an acceptable range.

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Although several of the following embodiments are directed to cooling a light source incorporated in a photocosmetic device, those having ordinary skill in the art will appreciate that the teachings of the invention can be employed to cool light sources
5 incorporated in other devices, such as, military, consumer or commercial lighting, industrial, medical and a variety of consumer devices. In general, the teachings of the invention are applicable to cooling any light source having a finite operational life time.

BRIEF DESCRIPTION OF THE DRAWINGS

10 Illustrative, non-limiting embodiments of the present invention will be described by way of example with reference to the accompanying drawings.

FIG. 1A is a schematic view of one example of an embodiment of a phototreatment device to treat a tissue according to aspects of the present invention;

15 FIG. 1B is a schematic view illustrating some aspects of a self-contained phototreatment device according to the present invention;

FIG. 2 is a schematic view of a phototreatment device including a consumable substance application system according to aspects of the present invention;

FIG. 3A is a cross-sectional view of a first example of a container comprises a first compartment fluidly connectable to a tissue, and a second compartment fluidly connectable to a phototreatment device;

25 FIG. 3B is a cross-sectional view of a second example of a container comprises a first compartment fluidly connectable to a tissue, and a second compartment fluidly connectable to a phototreatment device;

30 FIG. 3C is a cross-sectional view of a third example of a container comprises a first compartment fluidly connectable to a tissue, and a second compartment fluidly connectable to a phototreatment device;

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FIG. 4A is a schematic view of an exemplary embodiment of an application system for use with a replaceable container comprises a first compartment fluidly connectable to a tissue, and a second compartment fluidly connectable to a head of a phototreatment device;

FIG. 4B is a second schematic view of an exemplary embodiment of an application system for use with a replaceable container comprises a first compartment fluidly connectable to a tissue, and a second compartment fluidly connectable to a head of a phototreatment device;

FIG. 4C is a top view of an embodiment of a container;

FIG. 4D is a bottom view of an embodiment of a container;

FIG. 5A is a first schematic view of a phototreatment device having an indicia-based, detection and enablement system for use with a phototreatment device;

FIG. 5B is a schematic view of a container for use with an indicia-based detection and enablement system;

FIG. 6 is a schematic view of a container having a region to cool a heat dissipating element in a phototreatment device;

FIG. 7 is a block diagram that schematically depicts an exemplary embodiment of the invention in which the phase change medium is in direct thermal contact with a heated element incorporated in a photocosmetic device, to cool the heated element during operation of the device;

FIG. 8A is a block diagram that schematically depicts another exemplary embodiment of the invention in which a phase change material is employed to extract heat from a circulating fluid that cools a light source of a photocosmetic device;

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FIG. 8B is a block diagram that schematically depicts yet another exemplary embodiment having a removable heat exchanger that can be coupled to a photocosmetic device to transfer heat from a circulating cooling fluid, which extracts heat from a light source of the device, to a phase change material;

FIG. 9 is a cut-away, schematic perspective view of an exemplary handpiece of a photocosmetic device according to one embodiment of the invention;

FIG. 10 is a cut-away view of an ice cartridge coupled to a heat sink of the handpiece shown in FIG. 9;

FIG. 11 is a cut-away view of the cartridge shown in FIG. 10 prior to its engagement with the heat sink;

FIG. 12 schematically illustrates coupling of the cartridge of FIG. 11 with the heatsink of the handpiece of FIG. 10;

FIG. 13 schematically illustrates full engagement of the ice cartridge of FIG. 11 with the heat sink of the handpiece of FIG. 10;

FIG. 14 schematically shows a handpiece of a photocosmetic device of the invention that allows diverting a portion of a liquid generated as a result of melting of a phase change material onto a treatment area of a patient's skin;

FIG. 15A is a schematic perspective view of a cooling mechanism, coupling the cartridge of FIG. 11 onto a base unit of a photocosmetic device and utilizing a TE cooler provided in the base unit for freezing water contained in the cartridge into ice;

FIG. 15B is a schematic perspective view of another mechanism for cooling a cartridge containing a phase change medium;

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FIG. 16 is a block diagram that schematically illustrates a heat exchanger according to one embodiment of the invention that can removably and replaceably couple to a base unit of a photocosmetic device for cooling a fluid circulating between the base unit and a handpiece of the device for removing heat from a heated element incorporated in the handpiece;

FIG. 17 is a schematic perspective view of a cassette containing ice coupled to a base unit of a photocosmetic device for removing heat from a heat exchanger provided in the base unit;

FIG. 18A is a schematic perspective view of the cassette of FIG. 17 coupled to a receiving module in a base unit of the photocosmetic device;

FIG. 18B schematically illustrates the cassette and the receiving module of FIG. 18A in a disengaged state;

FIG. 19 is a cut-away perspective view schematically illustrating various components of the cassette of FIG. 18B;

FIG. 20 illustrates coupling of the cassette of FIG. 19 with a heat exchanger provided in the receiving module of FIG. 18B;

FIG. 21 schematically illustrates reduction of ice volume in a lower portion of an ice container of the cassette of FIG. 20 as the heat removed from a heated element of the photocosmetic device causes melting of the ice;

FIG. 22 schematically illustrates that upon melting of all of the ice in a lower portion of the container of FIG. 21, the generated water is accumulated in an upper portion of the container;

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FIG. 23 schematically illustrates a cooling device for removing heat from an optical transmissive element of a handpiece of a photocosmetic device according to one embodiment of the invention;

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FIG. 24A and FIG. 24B schematically illustrate alternative implementations of the cooling device of FIG. 23;

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FIG. 25A is a graphical representation of absorption spectra for some exemplary dyes suitable for use as markers of areas to be treated;

FIG. 25B is a graphical representation of exemplary absorption spectra for some exemplary, biocompatible dyes suitable for use as markers of areas to be treated;

Fig. 26 illustrates photo-enhancement of transcutaneous penetration of a retinol-containing preparation observed in *in vitro* conditions;

FIG. 27 is a schematic view of a system for measuring a speed of motion of a device on a tissue using a layer of marker material; and

20

FIG. 28 is a schematic illustration of another aspect of the present invention directed to visibly indicating an area that has been treated.

DETAILED DESCRIPTION

25 Aspects of phototreatment devices according to the present invention, for use in medical or non-medical environments, may include, for example, the following characteristics: (1) reduced thermal tissue damage (for example, it is desirable to avoid wounds and other skin injuries); (2) improved safety and efficacy (e.g., the device increases the likelihood that the appropriate consumable substances are used; that the device is in contact with particular tissue to be treated to avoid injury to sensitive tissues (e.g., the eyes); that the device is moved over tissue within a particular range of speeds; and that treated areas are not overtreated); (3) easy maintenance (preferably maintaining a device in useable condition and replacing expended parts can be easily accomplished);

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(4) easy manufacture (e.g., preferably the device is manufacturable in high volume); (5) low-cost manufacture and operation (e.g., preferably the device is available and operable at a reasonable price); (6) small package size (preferably the device is small and easily stored, for example, in a bathroom); (7) improved patient comfort during treatment (i.e., the device preferably results in reduced pain from light or mechanical action); (8) ease of use (e.g., providing a visual indication of regions of tissue that have been treated or regions to be treated); (9) it is capable of providing additional aesthetic benefits (e.g., application of a self-tanning substance). Currently available phototreatment devices have limitations related to one or more of the above characteristics.

The present invention provides systems and methods for using a phototreatment device with a substance, which can provide beneficial effects to the user such as cooling the target area, providing a means for generating a safety shut-off mechanism, marking the area that has been treated, delivering therapeutic effects to the patient, etc. The substance is contained within a compartment that is coupled to the phototreatment device. The substance can be an adjuvant substance, which is either consumable or re-useable.

I. Substances: Consumable and Reuseable

The container described in the present invention can be used with an adjuvant substance. An "adjuvant substance" as used herein is intended to include both re-useable substances (i.e., phase change coolant materials) and consumable substances (i.e., topical substances and disposable coolants).

A coolant may be any suitable transportable material capable of absorbing heat. For example, a coolant may comprise tetrafluorethan (R-134a), liquid CO₂, ice, frozen lotion, wax or frozen gel. In some embodiments, the coolant is a phase change material (i.e., a material that changes phase in response to addition or removal of heat). Example of phase transition substances include : cristallohydrates (45%CaCl*6H₂O: 55%CaBr*6H₂O ore KF*4H₂O), organic materials as HO(C₂H₄O)₈C₂H₄OH (PE Glycol), Caprilic acid, Hexadecane and Paraffin 5913. For example, the container may contain a pressurized gas in liquid phase (such that the liquid coolant is projected onto a target to absorb heat from the target, and in response to heat absorbed, the liquid changes to a gas), or a solid state material (e.g., a powder or granules or a block of material) with

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a melting temperature below the temperature of the target heat dissipating element. Various other phase changing materials may be used.

5 A topical substance may be any suitable transportable material to perform any suitable function. For example, a topical substance may enhance the efficacy of a phototreatment (e.g., coupling light from a source into a tissue, or by removing residual hairs), increase safety of a phototreatment device (e.g., cooling the tissue, indicating areas that have been treated, indicating rate of movement of the device over the tissue), provide comfort to a patient during or after a phototreatment (e.g., by containing mild
10 anesthetic ingredients and/or by cooling), or provide additional benefits for the skin and subcutaneous tissue (e.g., by moisturizing skin, tanning skin, ultraviolet (UV) protection, improving skin texture and tones, improvement of skin elasticity, reduction or prevention of cellulite, decreasing the appearance of cellulite, reduction and/or prevention of acne, reduction and or prevention of wrinkles, decreasing the appearance of scars, reduction and/or prevention of vascular lesions, reduction in pore size, oil
15 reduction in sebum secretion, reduction of sweat, reduction of odor, reduction or removal of body hair, stimulation of hair growth, etc.). In some embodiments, penetration of a tissue by topical substances may be photo-enhanced and/or the effect of the topical substance may be photo-enhanced by radiation from source 125.

20 According to some aspects of the present invention, a topical substance may comprise a lotion, water, alcohol, oil, gel, powder, aerosol, granular particles, cream, gel, wax, film or any other suitable substance. Exemplary topical substances are preferably: biocompatible; have a low absorption coefficient for the wavelength or wavelengths of light that effects a phototreatment (e.g., less than 1 cm^{-1}); and have a low
25 scattering coefficient for the wavelength of light that effects a phototreatment (e.g., less than 10 cm^{-1}).

Topical substances for use with phototreatment devices operated in contact with a tissue preferably have: a refractive index close to the refractive index of the epidermis (e.g., the index may be 1.3-1.6, and preferably 1.4-1.55); a high thermal conductivity
30 (e.g., greater than 0.1 W/m/K); and a good lubrication effect. It is to be appreciated that a topical substance can be applied to the treatment region by the patient or operator, or be dispensed from a suitable dispensing device. It is to be appreciated that a consumable substance may have multiple purposes and effects, for example, the

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consumable substance may operate both as a topical substance and a coolant. In such embodiments, a substance may be fluidly coupled to the tissue and the heat dissipating element, or the substance may be fluidly coupled only to the tissue but provide both
5 cooling and other benefits to the tissue.

In other aspects of the present invention, efficacy and/or safety of a phototreatment may be improved where the topical substance itself (which may or may not be a coolant) or a marker (added to the topical substance) is used to designate an area to be treated, facilitate detection of motion of a phototreatment device over tissue, and/or
10 facilitate measurement of speed of said motion.

Phase change materials can be used as re-useable substances. The phase transition of a phase change material can be from a solid phase to a liquid phase, i.e., melting of ice, or from a solid phase to a gas phase, i.e., sublimation of dry ice stored in a cartridge. The phase-change material can be employed for removing heat from the
15 light source. Ice is a particularly good choice for the phase change material because it exhibits a high latent heat of melting and is biologically and environmentally safe. It should, however, be appreciated that any other suitable phase change material can also be utilized in the practice of the invention. In some embodiments, a frozen mixture of water and an additive, such as salt or alcohol, can be used as the phase change material.

20 Other examples of the phase change material include gallium and wax. In general, a suitable phase change material preferably exhibits a relatively high latent heat of melting to allow efficient heat dissipation, and is biologically safe. In addition, the phase change material is preferably safe for release into the surrounding environment. Further, skin beneficial ingredients can be added to the phase change material to be released onto a
25 portion of the patient's skin during treatment of the skin by the photocosmetic device. Such ingredients can provide beneficial and/or therapeutic effects independent of the therapeutic effects provided by the exposure of the skin to light or heating or cooling provided by the photocosmetic device. Alternatively, the skin beneficial ingredients can be photo or thermally activated by the device to provide their intended beneficial effects.

30 A single or multi-use cartridge containing both phase change material and skin beneficial ingredients can be configured in many ways including a) a phase change material (such as ice) mixed with skin beneficial ingredients in a single chamber or b) a phase change material and skin beneficial ingredients located in two separate chambers.

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The cartridge can be located either in the base unit or the handpiece and can be designed to be replaceable by the user.

For a single-use cartridge, the user would simply replace the old cartridge with a new one prior to treatment. Assuming ice is used as the phase change material to cool the light source, a supply of single-use cartridges could be kept in the freezer and used as needed.

For a multi-use ice cartridge with separate chambers for the captive ice/water and beneficial ingredients delivered to skin, the water could be refrozen after use. The multi-use cartridge could be designed to contain enough skin beneficial ingredients for 10 (nominal) treatments. If a marker was mixed in with the skin beneficial ingredients and the device was designed to activate only when the marker was detected, then the user would be forced to replace the cartridge even though the water could again be refrozen.

The lotion dispensed on the skin can contain both skin beneficial ingredients and compounds designed to improve the thermal and optical contact between handpiece and skin. In the case of a handpiece designed for unidirectional scanning across the skin surface, the lotion can be deposited on the skin either pre or post laser irradiation. By depositing a lotion designed to improve thermal and optical contact prior to laser irradiation, improved safety and efficacy can be achieved. A lotion cooled by the ice in the cartridge could be applied to the skin post irradiation to make the treatment more comfortable for the user. Whether applied pre or post irradiation, the lotion will provide lubrication, which allows the handpiece to be easily scanned across the skin surface.

II. Phototreatment Devices Coupled to a Container

FIG. 1A is a schematic view of one example of an embodiment of a phototreatment device 100 to treat a target area or tissue 150, for example, skin. Typically, photocosmetic treatments involve treating a target area located within an epidermal or dermal layer. For example, in the case of hair removal, it may be desirable to heat a bulb 152 of a hair follicle 160. Phototreatment device 100 includes a base unit 120, an umbilical cord 132 (also referred to herein as a "cord"), and a handpiece 170. According to an aspect of the present invention, phototreatment device 100 also includes a replaceable container 130 containing a consumable substance comprising, for example,

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a coolant or a topical substance. In other embodiments, container 130 may contain a topical substance and be fluidly connected to tissue 150.

Base unit 120 may include a power supply 124 to power an electromagnetic radiation (EMR) source 125 (also referred to herein simply as a "source"), which effects a phototreatment. Power supply 124 may be connected to an external power source or an internal battery. EMR source 125 may be any source (e.g., a laser, a lamp, an LED, or collected sunlight) capable of producing electromagnetic radiation to effect any presently-known or later-developed phototreatment. Power supply 124 may be electrically coupled to handpiece 170 via cord 132. Cord 132 is preferably lightweight and flexible.

Handpiece 170 includes a treatment head 180 (also referred to as a "head") configured to be used in proximity to tissue 150, and a handle 190 that may be grasped by an operator to move head 180 in any direction across tissue 150. For example, head 180 may be pushed across the tissue in a forward direction 105 or pulled across the tissue in a backward direction 106. Handpiece 170 may be mechanically driven by a suitable mechanical apparatus or hand-scanned manually across tissue 150. Typically, during a given stroke (i.e., movement over tissue 150), contact will be maintained between head 180 and tissue 150 while head 180 is moved, although some phototreatments according to the present invention may be achieved without contact. Firm contact between head 180 and tissue 150 is preferable to ensure good thermal and optical contact therebetween. Phototreatment device 100 is further described in U.S. Application 10/154,756 filed May 23, 2002, entitled "Cooling System for a Photocosmetic Device," by Altshuler et al., the entirety of which is hereby incorporated by reference.

In the embodiment illustrated in FIG. 1, source 125 is located in base unit 120 and connected to head 180 via a light pipe (e.g., an optical fiber, not shown) in cord 132. The light pipe may extend through handle 190, or may be otherwise connected to head 180 to deliver light to tissue 150. In some embodiments, the source is located in the handpiece, for example, in the embodiment illustrated in FIG. 2 below, a source 252 is located in a handpiece 280.

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While the above embodiment of a phototreatment device is modular (i.e., having a separated base unit and handpiece), it is to be appreciated that phototreatment devices according to aspects of the present invention can be implemented in a self-contained unit, in which an entire phototreatment device is implemented as a handheld device.

FIG. 1B is a cross-sectional schematic of one embodiment of a self-contained photocosmetic device according to the present invention. Handpiece 101 comprises an optical source 155, an optical system 144, and a container 146 for a consumable substance. The device is shown in contact with a tissue region 150'. Optical system 144 couples light from light source 155 into a tissue region 150'.

A power supply 147 (e.g., battery or capacitor) supplies electrical current to optical source 155. In some embodiments, power source 147 may be charged via an electrical contact 151 or an electrical cord (not shown). An on/off button 143 controls the electrical power. A housing 153 may be used to enclose, protect, or mount one or more of the above parts. Optionally, a hair removal device 154 (e.g., a razor) may be located to remove hair prior to irradiation by light from optical source 155 to ensure that substantially no hair extends above the skin surface. Further details regarding self-contained devices are given in U.S. Application 10/154,756, incorporated by reference herein above. In some embodiments, container 130' is coupled to optical source 155 or an optical system 144.

As described in greater detail below, in some embodiments, containers 130 and 130' can contain an adjuvant substance. An "adjuvant substance" as used herein is intended to include both re-useable substances (i.e., phase change materials) and consumable substances (i.e., topical substances and coolants).

In one embodiment, container 130 or 130', shown in FIG. 1A and 1B, contains a coolant and is fluidly connected to a heat dissipating element of phototreatment device 100, 101 either in the base unit or in the handpiece (for example, heat dissipating element 222 illustrated in FIG. 2 below). The coolant may instead be or may also be fluidly connected to tissue 150, 150' to cool the tissue. The phrase "heat dissipating element" is defined herein to mean any element that dissipates heat. A heat dissipating element may be a heat source (e.g., EMR source 125 or power supply 124) or an element that dissipates heat from a heat generating element (e.g., a heat sink or thermally conductive electrode).

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FIG. 2 is a schematic illustration of a phototreatment device 200 according to aspects of the present invention. A handpiece 280 includes a source 252 located to direct light from a head 272 onto a target area 250 (e.g., an area of a patient's skin) on which a selected phototreatment is to be performed.

A replaceable container 210 includes a consumable substance, for example, a coolant 215, that may be fluidly connected to tissue 250 and/or a heat dissipating element 222 in handpiece 280 and/or a heat dissipating element in base unit 220 (not shown). A "fluidly connected" container is defined herein as a container configured and arranged to deliver a substance (e.g., a consumable substance) to a selected location (e.g., a tissue and/or a heat dissipating element). For example, a fluidly connected container may be directly connected to a selected location or may be connected via a conduit and/or a valve. In some embodiments, container 210 is fluidly connected to a selected location (e.g., a tissue or heat dissipating element) via a conduit 270. A consumable substance to be delivered may be any suitable transportable substance. For example, a transportable substance may be a gas, liquid, gel, powder, granules, or any substance capable of being delivered from a container to a selected location.

Consumable substances may provide any benefits as described above and may provide benefits such as improved moisture, tone, texture, skin color, or exfoliation. Additionally, for example, a consumable substance may have a suitable color or be capable of changing color after receiving light from a phototreatment device, for example, to identify regions of tissue that have been treated by a phototreatment device as described herein. As other examples, a consumable substance may be a fluorescent material for use in a measuring speed of the device over tissue as described herein, or may provide any of a variety of other benefits as will be apparent to one of ordinary skill in the art.

A conduit may allow flow of the consumable substance to only tissue 250 or only to a heat dissipating element 222. Alternatively, conduit 270 may be bifurcated to allow flow of the consumable substance to both tissue 250 through a branch 270a, and a heat dissipating element 222 through a branch 270b. Alternatively, container 210 may be coupled to two separate conduits, one to allow flow of the consumable substance to tissue 250, and one to allow flow to heat dissipating element 222. In some embodiments, conduit 270 may comprise rigid plumbing within the base unit 220, and

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may comprise flexible plumbing in the region of the umbilical cord 232 to allow a user to freely move and orient the handpiece 280. Conduit 270 may be located such that the consumable substance 215 is delivered onto an area of tissue 250 before, during and/or
5 after phototreatment light is directed on the area of tissue.

As mentioned above, where a consumable substance 215 is a coolant, it may be any substance capable of absorbing heat. Preferably, the coolant is capable of efficiently absorbing heat. In some embodiments, the coolant changes phase as a result of absorbing heat from heat dissipating element 222 or tissue 250. The coolant may be a
10 liquid that becomes gaseous; or a solid or gel that becomes liquid or gaseous. For example, the coolant may be a pressurized liquid, such as liquid carbon tetrafluoride or liquid CO₂, or the coolant may be a solid, such as ice, frozen lotion or frozen gel that evaporates and/or liquifies upon absorbing heat from a selected location (e.g., heat dissipating element 222 or tissue 250). In other embodiments, the coolant may be a
15 super-cooled liquid (i.e., liquid cooled below nominal freezing temperature of its principal component).

Consumable substance 215 may be pressurized using any known method such that the consumable substance may be projected onto a selected location upon release of the pressure via conduit 270. For example, consumable substance 215 may be
20 mechanically compressed by reducing the volume of container 210 (e.g., by a spring, repelling magnets, or other suitable apparatus for applying pressure). In some embodiments, consumable substance 215 is a liquified gas under pressure, where container 210 includes a portion of liquified gas 215 and a portion of gas 218. In some embodiments, the pressure in the container projects a portion of liquified gas 215 to a
25 selected location. Alternatively, any suitable consumable substance 215 may be pressurized and projected by adding any suitable pressurized gas 218.

It is to be appreciated that a consumable substance may include a combination of materials. For example, a consumable substance 215 may comprise a coolant and a topical substance such that the consumable substance may be applied to tissue 250 and a
30 heat dissipating element 222.

One or more valves 230, 233, 234 may be included to control the release of consumable substance 215. Valves 230, 233, 234 may be any valves controllable using electrical, mechanical, magnetic controls or any other suitable valves. In some

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embodiments, one or more of valves 230, 233, 234 may be controllable based on speed of movement across the skin as measured by a motion sensor 240, or a temperature measured at the skin by a temperature sensor 242 or a temperature measured at heat dissipating element 222 by a temperature sensor 243. Motion sensor 240 and temperature sensors 242 and 243 are described in greater detail in U.S. Application 10/154,756, incorporated by reference herein above.

Valves 230, 233, 234 may be located in any suitable location to control the release of consumable substance 215. In some embodiments, a valve 230 is connected to container 210 or located in base unit 220, thereby avoiding adding to the size and weight of umbilical cord 236 or handpiece 280. In other embodiments, one or more valves 233 and 234 are located in handpiece 280, proximate a selected location (e.g., proximate tissue 250 or a heat dissipating element 222). For example, locating one or more valves in a handpiece 280 allows a pressurized liquid coolant 215 to be maintained in a liquid state to facilitate projecting the coolant onto the selected location in a liquid state; accordingly, as described above, the liquid coolant may change phase as a result of heat absorbed from a selected location.

In some embodiments, valve 230 is a displacement valve connected to container 210, and base unit 220 has a corresponding pin to displace valve 230 such that upon proper positioning of container 210, valve 230 is activated and consumable substance 215 fills conduit 270. Optionally, container 210 and base unit 220 may be threaded such that container 210 is screwed into base unit 222.

In some embodiments, base unit 220 maintains container 210 in a specific orientation. For example, container 210 may be maintained in an orientation such that valve 230 is at the bottom container 230 (i.e., gravity allows consumable substance 215 to flow through valve 230).

Although only one container is illustrated, phototreatment devices comprising two or more containers each containing a consumable substance, such as coolants and/or topical substances, are within the scope of the invention. As one of ordinary skill will understand, in the case of two or more such containers, each of the containers is fluidly connected to one or more selected locations.

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According to some embodiments of the invention, two containers may be connected to a single conduit or separate conduits that meet at the same target location to allow the consumable substances in the two containers to be physically or chemically combined either prior to or upon arrival at the selected location. Allowing two or more topical substances to be mixed may provide a great many benefits. For example, the mixture of the topical substances may provide an improved topical substance or coolant. Additionally, the two or more topical substances may have longer shelf life if kept in separate containers, or the mixture of the topical substances may cause a chemical reaction providing different benefits than either substance alone. For example, the combining of the consumable substances may result in an endothermic reaction that provides cooling or an active substance for topical application (e.g., an exfoliant, hair removal substance or self tanning compound).

FIG. 3A is a cross-sectional side view of an example of a container 300 according to an aspect of the invention. Container 300 comprises a first compartment 310 fluidly connectable to a tissue, and a second compartment 320 fluidly connectable to a head or base unit of the phototreatment device. A "fluidly connected compartment" is defined as a compartment configured and arranged to deliver a consumable substance to a selected location. For example, a fluidly connected compartment may be directly connected to a selected location or may be connected via a conduit and/or a valve, as described above with respect to FIG. 2. A "fluidly connectable compartment" is defined herein to be a compartment capable of being arranged to deliver a consumable substance to a selected location. It is to be appreciated a fluidly connectable compartment may provide for the flow of liquids, gases, gels, or suitable solids (e.g., powder or granules).

First compartment 310 and second compartment 320 each contain a corresponding consumable substance 312 and 322. Consumable substances 312 and 322 may be any consumable substances suitable for use with a phototreatment device as described herein. In some embodiments, at least one of consumable substances 312 and 322 is suitable for application on a tissue as a topical substance which may or may not cool the tissue and the other is a coolant for a heat dissipating element as described above with reference to FIG. 2.

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First compartment 310 and second compartment 320 may be separated by any divider 330 capable of separating consumable substances 312 and 322. The divider may be rigid or flexible; divider 330 may be fixed to a wall 302 of container 300, or may be moveable relative to wall 302. In some embodiments, there may be more than one divider present.

In some embodiments, first compartment 310 and second compartment 320 are in pressure communication. The phrase "pressure communication" is defined herein to mean that a pressure in one of first compartment 310 and second compartment 320 is applied to the other compartment, respectively. Preferably, pressure communication allows the first compartment 310 and second compartment 320 to have equal pressure therein.

First compartment 310 and second compartment 320 may be separated by a divider 330 capable of maintaining pressurized gas in one or both of compartments 310 and 320. For example, to achieve pressure communication, divider 330 may be fixed to wall 302 and have a valve 332 to allow the flow of pressurized gas (e.g., a propellant) from compartment 320 to compartment 310; alternatively, divider 330 may be moveable relative to wall 302 (e.g., the divider may be a plunger, such as a plunger used in a syringe) such that divider 330 moves relative to wall 302 to maintain a pressure in compartments 310 and 320.

Although first compartment 310 and second compartment 320 are illustrated as being disposed end to end, any suitable arrangement in which compartments 310 and 320 are fluidly connectable to a tissue and a heat dissipating element, are within the scope of this invention. Further exemplary embodiments of containers having a first compartment and second compartment in pressure communication are illustrated below with reference to FIGs 3B and 3C. It is to be appreciated that any of the embodiments illustrated in FIG. 3A-3C may include an indicator as described herein.

FIG. 3B is a cross-sectional view of a second example of a container 340 that includes a first compartment 342 fluidly connectable to a tissue through a port 341 (e.g., a valve) and having a consumable substance 343, and a second compartment 344 fluidly connectable to a heat dissipating element through a port 347 and having a consumable substance 345. First compartment 342 and second compartment 344 are disposed side-by-side, and separated by a wall 349 and a divider 346. Divider 346 is moveable

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relative to walls 348 and 349 such that first compartment 342 and second compartment 344 are in pressure communication. As an alternative to a moveable divider 346, a valve may be used to provide pressure communication.

5 While FIG. 3B was discussed with compartment 342 fluidly connectable to a tissue and compartment 344 fluidly connectable to a heat dissipating element, respectively, it is to be understood that first compartment 342 may be fluidly connectable to a heat dissipating element and/or a tissue, and second compartment 344 may be fluidly connectable to tissue and or heat dissipating element.

10 FIG. 3C is a cross-sectional view of a third example of a container 350 that includes a first compartment 352 having a consumable substance 353 fluidly connectable to tissue through a port 351; and a second compartment 354 having a consumable substance 355 fluidly connectable to a head of a phototreatment device through a port 357. First compartment 352 and second compartment 354 are separated
15 by a flexible divider 356 such that first compartment 352 and a second compartment 354 are in pressure communication. For example, flexible divider 356 may be a plastic bag.

 Divider 356 allows a pressurized gas (e.g., a propellant) to be maintained in a first of compartments 352 and 354, and maintains a pressure in the other of compartments 352 and 354. Divider 356 is compressed or expanded (depending on
20 which of compartments 352 or 354 has greater pressure).

 While FIG. 3C was discussed with compartment 352 fluidly connectable to a tissue and compartment 354 fluidly connectable to a heat dissipating element, respectively, it is to be understood that compartment 352 may be fluidly connectable to a heat dissipating element and/or tissue, and 354 may be fluidly connectable to tissue
25 and/or a heat dissipating element.

 FIG. 4A is a schematic of an exemplary embodiment of an application system 400 for use with a container 405 comprised of a first compartment 410 fluidly connectable to a tissue, and a second compartment 420 fluidly connectable to a head 480 of a phototreatment device.

30 In FIG. 4A, a first fluid connection is made to first compartment 410, and a second fluid connection is made to second compartment 420. First compartment 410 of container 405 may be fluidly connected to tissue 450 in any suitable manner, such as described above with reference to FIG. 2, and a second compartment 420 may have a

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fluid connection to a heat dissipating element 422 of head 480, such as described above with reference to FIG. 2.

In FIG. 4A, valves 430 and 432 may be used to control the flow of a consumable substance 424. One or more valves 434, 435, 436 may be used to control the flow of consumable substance 414 from first compartment 410. Valve 435 may be a displacement valve, and base unit 425 may have a pin 437 which displaces valve 435, such that upon displacement of the valve 435, consumable substance 414 fills conduit 433. In some embodiments, pin 437 is located on a spring-activated door 428, such that when door 428 is closed, pin 437 activates valve 435. One or more additional valves 434, 436 may be added to control the flow of consumable substance 414, for example, flow may be controlled based on speed of movement across the skin as measured by a motion sensor 440, or a temperature measured at the skin by a temperature sensor 442 or a temperature measured at a heat dissipating element 422 by a temperature sensor 443. For reasons described above, one or more of valves 432 and 436 may be located proximate a selected target location.

In some embodiments, base unit 425 maintains container 405 in a specific orientation. For example, container 405 may be maintained in an orientation to facilitate flow of fluid 424 through a conduit 470 by pressure generated by a propellant.

In some embodiments, a connection 444 by which container 405 connects to base unit 425 is different than a connection 446 by which container 405 connects to base unit 425. Referring to FIGs. 4C and 4D, connections 444 and 446 are illustrated in greater detail. In FIG. 4C, 490 is a top view of container 405 and in FIG. 4D 492 is bottom view of container 405. For example, connections 444 and 446 may have different characteristics, such that each of valves 435 and 430 is activated only if the connections 444, 446 are appropriate. Such connections are commonly referred to as "lock and key" mechanisms. Accordingly, selective activation of valves 435 and 430 is achieved, such that consumable substance 414 is prevented from reaching heat dissipating element 422 and consumable substance 424 is prevented from reaching tissue 450. For example, this may prevent accidental upside-down or reverse insertion of container 405 in system 400, and thereby improve safety and efficacy (e.g., the device connections 444, 446 reduce the likelihood that inappropriate consumable substances are used).

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5 A lock and key mechanism may achieve selective activation by configuring connections 444 and 446 based on characteristics including, but not limited to shape, size, and threads. For example, only if a connection 444 or 446 is appropriate, is the corresponding valve 435, 430 activated (e.g., pin 437 (shown in FIG. 4A) activates a displacement mechanism of a valve 435). Alternatively the lock and key mechanism may achieve selective activation based on electrical, magnetic, or piezoelectric characteristics. For example, only if a connection 444 or 446 provides an appropriate electric or magnetic signal, is the corresponding valve activated.

10 FIG. 4B is a schematic view of an exemplary embodiment of an application system 425 for use with a container 405' comprising a first compartment 410' fluidly connectable to the tissue (not shown), and a second compartment 420' fluidly connectable to a head (not shown) of a phototreatment device (e.g., container 300 shown in FIG. 3A above). Application system 425' has a spring-loaded lid 428' with a conduit 15 433' to the tissue and a conduit 470' to a heat dissipating element. Consumable substances within container 405' may be applied to the target location as described with respect to Fig. 2 above.

FIG. 5A is a schematic view of a phototreatment device 500 having an indicia-based, detection and enablement system. Phototreatment device 500 includes a 20 container 510 comprising a consumable substance 512 and an indicator 520. Container 510 is fluidly coupled to the head 580 and/or the tissue to be treated. Phototreatment device 500 also comprises an indicia detector system 522 comprising a detector 524.

Indicator 520 may be any indicator of a consumable substance 512. Indicator 520 may be an optical indicia, a magnetic indicia, an electronic indicia, a piezoelectronic 25 indicia or any known or yet to be developed indicia. Indicator 520 may be attached to the outside of the container 510, may be integrated into the material comprising container 510, or may be within container 510 and detectable through the material comprising container 510. Indicator 520 may contain information identifying any aspect of the consumable substance. For example, the indicator 520 may indicate a 30 manufacturer of the consumable substance or container 510, a manufacturing lot number of the consumable substance or the container, a date on which the container or contents of the container were made, the location where the container or contents of the container were made and/or an expiration date of the contents. Indicator 520 can also indicate the

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amount of consumable substance within container 510 both when it is connected to the phototreatment device and as the consumable substance is used.

In some embodiments of phototreatment device 500, indicator detector system 522 simply detects the presence of a container. For example, source 523 may project light onto container 510, such that detector 524 detects light reflected from container 510; alternatively, light projector 523 may project light to a detector 525, such that in absence of container 510 light is detected by detector 525, and in the presence of container 510, light is prevented from reaching detector 525. Alternatively, a mechanical detector 528 may be displaced by container 510 to detect the presence of container 510.

In some embodiments, indicator detector system 522 obtains information from the indicator 520 using a suitable method of reading indicia. For example, detector system 524 may comprise an optical detector, magnetic detector, an electronic detector, a piezoelectronic detector, or any other suitable indicia detector to detect and/or read any known or yet to be developed indicia. In some embodiments, indicator detector system 522 may include a source 523 (for example, optical detectors systems such as bar code systems may require an optical source).

Detector system 522 may also include electronic components that can enable or disable the phototreatment device 500. For example, after reading indicator 520, electronic components within detector system 522 may determine if the indicia is one of an acceptable set of indicia. If the indicia is acceptable, then detector system 522 may enable phototreatment device 500, or any component of phototreatment device 500. If the indicia is not acceptable, then detector system 522 may disable or not enable phototreatment device 500. For example, phototreatment device 500 may be enabled through an electronic switch within or coupled to detector system 522, or through additional electronics within or coupled to detector system 522 through an enabling signal. Detector system 522, therefore, can prevent an inappropriate container 510 from being used with phototreatment device 500, thereby protecting the system and the person being treated. Detector system 500 may be one of several safety systems within phototreatment device 500 and the several safety systems may provide a safety loop whereby if any one safety system detects a problem, device 500 is disabled or is not enabled.

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Optionally, indicator detector system 522 may be coupled to a processor 550, and processor 550 may enable or disable phototreatment device 500. In addition, processor 550 may be coupled to a memory 560. Indicator detector system 522 may
5 detect indicator 520, and the processor may record the detected indicia in memory 560 and/or the processor may display data included in the indicia. Data detected by detector 524 may be processed by phototreatment device 500 or any other device (such as a diagnostic device). The processing of the data by processor 550 may occur before, after, simultaneously, or instead of storage in memory 560. The data processed by processor
10 550 may be used to configure or adjust parameters of phototreatment device 500. For example, the fluence, pulse width, wavelength or any other parameter of phototreatment device 500 may be changed depending upon the type of container detected through the indicator as being connected to the phototreatment device. As a result, multiple acceptable indicia may correspond to different containers containing different
15 consumable substances and the processor may change the parameters of the phototreatment device to optimize the treatment for each particular consumable substance. In addition, each container and/or consumable substance may correspond to a different type of treatment and the processor detection of a particular container would correspond to a particular treatment for which the processor would adjust the parameters
20 accordingly.

In addition to or instead of the indicator detector system 522, one or more detectors 528, 530, 532 may be arranged to identify the consumable substance 512. Detectors 528, 530, 532 may be any suitable detector, such as those described above, for
25 identifying consumable substance 512. Detectors 528, 530, 532 may use any physical, optical, electrical, mechanical, chemical, or other mechanism for identifying a characteristic of consumable substance 512, to thereby identify consumable substance 512. For example, a detector may determine the chemical composition, the color, or the viscosity of a consumable substance.

Alternatively, a marker may be added to consumable substance 512 to identify
30 the consumable substance, such that the marker is detected by detectors 528, 530, 532. The marker may be any suitable additive, such as those described above, capable of detection by any of the above described methods and mechanisms. For example, the marker may be a dye capable of optical detection, or the marker may have a detectable

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chemical composition, or may have detectable magnetic properties, or it can be a fluorescent material such that the additive is detected by projecting light onto the additive.

5 Detectors 528, 530, 532 may be located at any appropriate location. For example, a detector (e.g., detector 530) may be located inside container 510 or integrated with container 510 and coupled with detector system 522 or processor 550 in phototreatment device 500. The detector may be coupled to detector system 522 by an electrical connection (e.g., metal contacts with or without a wire to detector system 522)
10 or by wireless communication (e.g., electromagnetic pulse(s)). Alternatively, or in addition to detector 530, a detector 528, 532 may be located within phototreatment device 500 and in the path of the consumable substance 512 such that they can identify the consumable substance or marker as it enters phototreatment device 500 from container 510 (e.g., detector 528) or as it enters handpiece 580 (e.g., detector 532). It is
15 to be appreciated that any of detectors 528, 530, 532 can be electrically coupled to any one or more of detector system 522, processor 550, and a memory 560, for example, a bus line or other electrical connection may be implemented.

After identifying the consumable substance or marker, detector system 522 or processor 550 may determine if the consumable substance or marker is one of an
20 acceptable set of consumable substances or markers. If acceptable, then detector system 522 or processor 550 may enable phototreatment device 500, or any component of phototreatment device 500. If the consumable substance or marker is not acceptable, then detector system 528 or processor may disable or not enable phototreatment device 500 or a selected one or more components of phototreatment device 500. Identifying the
25 consumable substance or marker, ensures that the phototreatment device will only function with a container filled with appropriate consumable substances or markers, thereby further protecting the phototreatment device from damage and the person being treated.

In some embodiments of phototreatment device 500, a communications port 570
30 is included to enable data to be transmitted from phototreatment device 500 to external computer systems. For example, the data may be transmitted for diagnostic purposes, or for assisting a user in operating the device. Communications port 570 may be wired or wireless.

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FIG. 5B is an enlarged view of a container 510 for use with an indicator-based detection and enablement system. Container 510 comprises a compartment 502 to contain a consumable substance (not shown) therein. Compartment 502 is fluidly connectable to a head or base unit of a phototreatment device or tissue (not shown). Container 510 further comprises an indicator 520.

Container 510 may be any container capable of containing a consumable substance. For example, container 510 may be a two-compartment container (shown in FIGs. 3A-3C) and/or a container having a thermally conductive region (shown in FIG. 6); however, container 510 is not limited to such containers. The consumable substance may be any consumable substance suitable for use with a phototreatment device. For example, consumable substance may be a topical substance and/or coolant as described herein above.

III. Photocosmetic Device Cooling Systems

FIG. 6 is a schematic view of a container 600 having a region 610 configured and arranged to cool a heat dissipating element 620 in a phototreatment device. Container 600 is arranged to be in thermal contact with heat dissipating element 620. Container 600 may be constructed of any thermally conductive material (e.g., a metal), comprising a compartment 640 and configured to contain a substance capable of cooling heat dissipating element. The substance can be any suitable substance, for example, ice, frozen gel, frozen lotion or other coolant.

In some embodiments, the substance is not a consumable substance (i.e., the substance is not a topical substance and it remains in the container). In such embodiments, the container may be re-used (i.e., after the container has reached a temperature where it can no longer adequately cool, it may be re-cooled or re-frozen).

In some embodiments, container 600 is configured to contain a liquified gas 650 that is maintained in a liquid state by pressure. Container 600 is fluidly connectable to a head of a phototreatment device and/or tissue (not shown) via any suitable connector 602. According to well known laws of thermodynamics, as liquified gas 650 is released from container 600, some of the liquified gas within compartment 640 will experience a phase change from liquid to gas, and thereby reducing the temperature of liquified gas 650 and that of at least region 610 of container 600. Accordingly, region 610 may be

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thermally coupled to a heat dissipating element 620 to remove heat from the heat dissipating element. Liquified gas 650 may be a coolant and/or a topical substance as described herein, which is capable of being pressurized to form a liquified gas.

5 In some embodiments of container 600, only region 610 is constructed of a thermally conductive region, so that heat is selectively dissipated at region 610, and the remainder of container 600 is thermally insulated such that heat selectively flows through region 610. In some embodiments, region 610 has a thickness T that is larger than the thickness t of other regions of container 600 and, optionally, region 610
10 comprises a textured surface 612 for improving heat transfer.

 With reference to FIG. 7, in some embodiments of the invention, a phase change material 710, such as ice, is in thermal contact with a heat transfer element 712 incorporated in a photocosmetic device, for example, in a handpiece of such a photocosmetic device, that transfers heat from a heat generator, e.g., light source 714,
15 electronics and contact tip 714a to the phase change material during the operation of the light source and/or between operation. The transferred heat can cause a phase transition in the phase change material, for example, a transition from a solid phase to a liquid phase, thereby providing a mechanism for removing heat from the light source. In other words, the heat extracted from the light source by the heat transfer element 712 which
20 thermally contacting to tip 714a and electronics provides the heat required for causing the phase transition of the phase change material. In this exemplary embodiment, the phase change material is contained within an enclosure 716 having an opening 716a that allows direct contact between the phase change material and the heat exchanger. The surfaces of the phase change medium and the heat transfer element that are in contact
25 with one another are preferably shaped to optimize heat transfer from the heat transfer element to the phase change medium. In general, the enclosure 716 is preferably formed of a thermally low conductive material. In some embodiments, the phase change material 710 can be in thermal contact with the heat transfer element 712 via a portion of the enclosure 716. In other embodiments, the phase change material can be in direct
30 contact with the light source without the intervention of the heat transfer element 712. An optical element 714a, which directs radiation from the light source 714 to a portion of a patient's skin, can also be in thermal contact with the heat transfer element to ensure that its temperature remain in a range that is not damaging to the patient's skin.

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With reference to FIG. 8A, in another exemplary embodiment of the invention, a circulating cooling fluid, such as water, is utilized to remove heat from the heat transfer element 812, which in turn extracts heat from the light source 814 (or other heated element). A pump 818 circulates the cooling fluid from the heat transfer element 812 to another heat exchanger 820 that transfers heat from the cooling fluid to the phase change material 810, such as ice, that is in thermal contact with the heat exchanger 820. The transferred heat is dissipated by causing a phase transition of the phase change material, for example, from a solid state to a liquid state. In this exemplary embodiment, the second heat exchanger 820 can be incorporated in the photocosmetic device, for example, in a base unit thereof. The phase change material can be prepared for use in the device externally, and then be placed in thermal contact with the heat exchanger 820 to extract heat therefrom via a phase transition to a different state. Subsequent to the phase transition, the material can be removed from the photocosmetic device, and the cycle can be iterated. For example, when the phase change material is ice, a selected quantity of water can be frozen in an external freezer to form ice, and the ice can then be placed in thermal contact with the heat exchanger 820. Upon melting of the ice, the generated water can be removed. Alternatively, a cooling device, such as a thermoelectric (TE) cooler can be provided in the photocosmetic device for re-generating the phase transition material in a state suitable for extracting heat from the heat exchanger, without removing the material from the photocosmetic device, after a phase transition caused by the heat transferred from the heat exchanger to the phase change material. That is, in this example, the TE cooler can freeze the water back into ice.

With reference to FIG. 8B, in another embodiment, a circulating fluid transfers heat from the heat transfer element 812, which is thermally coupled to the light source 814 (or other heated element), to another heat exchanger 822, which is in thermal contact with a phase change material, such as ice. The heat exchanger 822, together with the phase change material 810, can be coupled to the photocosmetic device in a removable and replaceable fashion. For example, upon a phase transition of the phase change material as a result of heat extracted from the circulating fluid, the heat exchanger and the phase change material can be removed from the photocosmetic device to be prepared for re-use in the device. For example, the heat exchanger together with the phase change material can be placed in an external freezer to cause a phase transition

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of the phase change material into a state suitable for extracting heat from the heat exchanger. A unitary structure can be utilized for housing the heat exchanger and the phase change material in thermal contact with one another. Alternatively, the heat exchanger 822 and the phase change material can be housed in separate enclosures that
5 can be coupled together so as to provide good thermal contact between the heat exchanger and the phase change material.

Various exemplary implementations of the above embodiments are described below. It should be understood that the following embodiments are presented for
10 providing further elucidation of salient features of the invention, and are not intended to be limiting of the types of implementations that can be employed to practice the invention.

By way of example, with reference to FIG. 9 and FIG.10, an exemplary handpiece 924 of a photocosmetic device according to one embodiment of the invention
15 includes a light source 1026, e.g., a diode laser or LED or lamp, that is positioned between positive and negative electrodes 1028 and 1030 and is in electrical contact with these electrodes. The diode laser can be clamped between the two electrodes, or can be secured to the electrodes by any other suitable method that ensures good thermal and electrical contact between the diode laser and the electrodes, or only the positive
20 electrode. The electrodes 1028 and 1030 supply electrical power to the diode laser, and are preferably formed of a material, e.g., copper, that has good thermal conductivity. The diode laser 1026 and/or the electrodes are in thermal contact with a heat transfer element 1032 (herein also referred to as a heat sink) that transfers waste heat generated by the laser to a phase change material, such as ice, as described in more detail below.
25 The heat sink 1032 can be formed of any suitable material having good thermal conductivity. For example, the heat sink 1032 can be formed of copper, aluminum, diamond or any other suitable material.

The exemplary handpiece 924 further includes an optics assembly 1034 having an optical transmissive element 1036, for example, a sapphire window, that receives
30 radiation emitted by the laser through an input surface, and delivers the radiation through an output surface to a portion of a patient, for example, a patient's skin. The input surface of the transmissive element is typically located at close proximity of the laser without having direct contact therewith (in some embodiments, the input surface

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can have direct contact with the light source). Further, the transmissive element is preferably in thermal contact with the heat sink 1032, and is formed of a thermally conductive material that allows removing heat from a portion of a patient's skin that is treated with radiation provided by the light source 1026.

The exemplary heat sink 1032 can couple to the diode laser 1026 and/or the electrodes 1028/1030. A tubular housing 1033, which extends from the heat sink block, can couple to a cartridge 938 in which a quantity of a phase change material, such as ice, is stored for cooling the heat sink 1032, as described in more detail below.

The handpiece 924 is typically connected via an umbilical cord (not shown) to a base unit (not shown) that can include, e.g., a power supply and associated electronics for powering the light source and providing selected control functions. Alternatively, the handpiece 924 may be the entire photocosmetic device including battery power.

The exemplary cartridge 1038, in which a phase change material is disposed, can be removably and replaceably coupled to the heat sink 1032 via the tubular housing 1033. The cartridge 1038 can hold a selected quantity of a phase change material, which in preferred embodiments of the invention is selected to be ice. As discussed above, ice is a particularly good choice for the phase change material because it exhibits a high latent heat of melting and is biologically and environmentally safe. It should, however, be appreciated that any other suitable phase change material can also be utilized in the practice of the invention. Further, skin beneficial ingredients can be added to the phase change material to be released onto a portion of the patient's skin during treatment of the skin by the photocosmetic device. Such ingredients can provide beneficial and/or therapeutic effects independent of the therapeutic effects provided by the exposure of the skin to light, heating or cooling provided by the photocosmetic device. Alternatively, the skin beneficial ingredients can be photo or thermally activated by the device to provide their intended beneficial effects. As discussed in more detail below, the cartridge 1038 can be a disposable element, or alternatively, can be a multi-use element.

With reference to FIG. 11, the exemplary cartridge 1138 has a generally cylindrical shape (circular, elliptical, rectangular) and includes a hollow tubular housing 1140 in which a quantity of ice, or other suitable phase change material, can be stored. A membrane seal 1142, which is disposed at a proximal end of the cartridge 1138, and another seal 1144, herein referred to as a piston seal, which is disposed at a distal end of

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the cartridge, cooperatively ensure that the ice remains confined within the cartridge before its engagement with the heat sink 1132. A volume 1146 disposed behind the seal 1144 provides a space for collecting water, via a liquid return port 1148, that is
5 generated as a result of melting of the ice, as described in more detail below.

The membrane seal 1142 is attached to an annular sealing ring 1150 that can provide a seal between the cartridge 1138 and the heat sink 1132 upon coupling of the cartridge with the heat sink. The annular sealing ring 1150 and the membrane seal 1142 can be formed as two separate components and joined together, or alternatively, they can
10 be formed as a unitary structure.

Referring to FIG. 12 and FIG. 13, the cartridge 1238 can be inserted into the hollow tubular housing 1233 and pushed forward to fully engage with the heat sink. As shown in FIG. 12, as the cartridge is pushed forward, an edge 1233a of the tubular housing 1233 pushes back on the annular sealing ring 1250, thereby causing the
15 membrane seal 1242 to tear and to move towards the annular sealing ring 1250. The tearing of the membrane seal 1242 exposes a surface of the ice, or other phase change material stored in the cartridge, initially covered by the membrane seal. Upon full engagement of the cartridge with the heat sink (FIG. 13), this exposed surface will be in thermal contact with a back surface of the heat sink block 1232 to allow heat generated
20 by the light source to flow from the heat sink to the ice. The transferred heat causes melting of the ice at the ice-heat sink interface, thereby removing heat from the heat sink. In other words, melting of the ice provides the mechanism for dissipating the heat generated by the light source.

The surface of the heat sink that is in contact with the ice is preferably shaped so
25 as to ensure a substantially uniform contact area between the ice and the heat sink at the ice/heatsink interface during operation of the handpiece. In general, this shape allows the contact surface to be a surface of constant temperature. For example, this heat sink surface may have a generally convex shape that substantially conforms with a generally concave shape of the corresponding ice surface. Those having ordinary skill in the art
30 will appreciate that other shapes can also be utilized to optimize the ice/heat sink contact. In addition, this surface can include one or more ports, e.g., in the form of slits, for removing fluid (liquid or gas), generated as a result of phase transition of the phase

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change medium, from the interface of the heat sink and the phase change medium, thereby preventing formation of a liquid or a gas layer at this interface.

During operation of the handpiece, as heat from the light source is transferred to the ice via the heat sink 1232, water is generated at the ice/heat sink interface. To ensure that the heat sink is in contact with ice rather than water, in preferred embodiments of the invention, the ice cartridge is continuously or discrete translated towards the heat sink during operation and/or between operations of the handpiece. Further, the generated water is moved from the ice/heat sink interface to the volume 1246 at the distal end of the cartridge in a manner described in more detail below.

A number of mechanisms can be utilized for translating the ice cylinder towards the heat sink. Without limitation, such mechanisms can include: a) a spring pressing against the back of the ice cylinder at the distal end of the cartridge, e.g., pressing against the piston seal 1144, b) a motorized linear screw, c) a compound that reacts with the water collected in the volume 1146 to generate a gas, e.g., CO₂, to drive the ice forward with gas pressure, d) a foam, or other compound, disposed in the space 1146 whose volume expands as it absorbs water, e) a separate pressurized cylinder or pump that supplies gas for driving the ice forward by gas pressure, f) a permanent magnet or an electromagnet, g) a piezo motor, h) a motor, which mounted inside handpiece or main units and delivery pressure to melting substance through wire, i) pressure can be applied from the hand/fingers of operator with simultaneously activating of light sources, j) pressure from gas chamber heated by electronics or light sources. For example, for manual application of pressure, a portion of the handpiece 924 can be made of a flexible material or otherwise compressible. Cooling efficiency and temperature of light sources and skin can be regulated by changing of the pressure.

With reference to FIG. 9 and FIG. 12, the exemplary handpiece 924 further includes a vacuum/pressure pump 952 for pumping the water generated due to melting of the ice, or other fluid when a phase change material other than ice is employed, from the ice/heat sink interface, via a return manifold 954, to the volume 1246. More particularly, the pump 952 pumps the water through internal channels 1256 provided in the heat sink and via the return manifold 954 and the piping 958 into the space 1246 at the distal end of the cartridge. This advantageously allows a more efficient thermal

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contact between the remaining ice, which is translated forward to be in contact with the heat sink, and the heat sink.

5 With reference to FIG. 14, in some embodiments of the invention, the return manifold 1454 can include a plurality of ports 1460 through which at least a portion of the water generated at the ice/heat sink interface can be diverted onto a portion of a subject's skin, which is under treatment via radiation provided by the handpiece. In addition, selected additives, such as various therapeutic, cosmetic or cleaning agents can be added to the water that is diverted onto the skin surface.

10 In this exemplary embodiment, the optically transmissive element 1036 of the optics assembly 1034 is in thermal contact with the heat sink 1032. This allows simultaneous cooling of the light source and the optical element 1036. During operation of the handpiece, the optical element 1036 can be in contact with a portion of a patient's skin. Hence, cooling of the optical element 1036 provides a mechanism for removing
15 heat from the patient's skin to ensure that the temperature of the treatment area remains within an acceptable range, for example, below about 30 °C.

In some embodiments of the invention, the laser diode 614, or other light source incorporated in the handpiece 924, may operate at a sufficiently high temperature such that heat transferred via the heat sink to the ice will not only cause melting of the ice into
20 water but it may also cause evaporation of at least a portion of the generated water. The evaporation of the water, in other words, the phase transition of the water from a liquid phase to a gas phase, can help in removing heat from the heat sink. In some embodiments, the evaporation temperature of water can be decreased by lowering the ambient pressure in a volume in which water is generated as result of melting of ice,
25 e.g., a volume at the interface of the heat sink and the ice. For example, a pump can provide a partial evacuation of air from this volume to lower the evaporation temperature.

The ice in the cartridge can be generated in a variety of different ways. For example, with reference to FIG. 15A and FIG.15B, the cartridge can be designed to
30 couple to a thermoelectric (TE) cooler 1561 provided in a base unit 1562 of the photocosmetic device. Alternatively, a TE cooler, adapted for coupling to the cartridge, can be provided in an accessory unit. In another approach, the ice can be generated by placing the cartridge in a freezer. Alternatively, a semi-permanent ice cartridge can be

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incorporated into the handpiece, and the entire handpiece can be placed in a freezer to freeze water disposed in the cartridge into ice.

The cartridge can be designed as a disposable unit that is discarded after one use.

5 Alternatively, the cartridge can be utilized as a reusable unit.

Although in the above exemplary embodiment, the cartridge containing the phase change material is incorporated in the handpiece, in other embodiments, the heat can be transferred from the heated element in the handpiece to another module in which the transferred heat can be dissipated by causing the phase transition of a selected material,
10 e.g., melting of ice,

It should be understood that phase change materials other than ice can be employed in a manner described above to extract heat generated by the light source. For example, in some embodiments, a frozen mixture of water and an additive, such as salt or alcohol, is provided in the cartridge as the phase change material. Other examples of
15 the phase change material include gallium and wax. In general, a suitable phase change material preferably exhibits a relatively high latent heat of melting to allow efficient heat dissipation, and is biologically safe. In addition, the phase change material is preferably safe for release into the surrounding environment.

In some embodiments of the invention, rather than utilizing the phase transition
20 of a phase change material from a solid phase to a liquid phase, the sublimation of a phase change material, such as dry ice stored in the cartridge, from a solid phase to a gas phase is employed for removing heat from the light source.

In another aspect, the present invention provides a heat exchanger that utilizes a phase change material, such as, ice, for efficiently extracting heat from a heated element
25 incorporated in the handpiece of a photocosmetic device. By way of example, FIG. 16 illustrates a heat exchanger 1664 according to one embodiment of the invention that includes a substantially hollow housing 1666, formed, for example, of metal or plastic. A plurality of structures 1668 having selected geometrical shape are disposed within the housing 1666. Each of the structures 1668 provides an enclosure for storing a selected
30 quantity of a phase change material, such as ice. The structures can have a variety of different geometrical shapes, such as, spherical, cylindrical, or an elongated serpentine shape, or any other suitable shape. Further, the structures 1668 can have different sizes for storing different volumetric quantities of the phase change material. In general, the

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shapes and the sizes of these internal structures, which function as reservoir for a phase change material, are chosen so as to maximize their surface area to volume ratios, thereby enhancing the efficiency of heat exchange, as discussed in more detail below.

5 An internal volume of the heat exchanger 1664 surrounding the structures 1668 is filled with a fluid having a freezing temperature that is lower than the phase transition temperature of the phase change material contained within these structures. For example, when the phase change material is selected to be ice, the filling fluid can be a mixture of water and alcohol, or water in which a selected quantity of salt is dissolved,
10 having a freezing temperature that is lower than the melting temperature of ice. As described in more detail below, during operation of the photocosmetic device, a cooling fluid that has extracted heat from a heated element of the device can circulate through the heat exchanger 1664, via ports 1670 and 1672 that allow ingress and egress of the cooling fluid into and out of the heat exchanger. The heat carried by the cooling fluid
15 causes a phase transition of the phase change material contained within the structures 1668, thereby lowering the temperature of the cooling fluid, which can then be employed again to extract heat from the heated element.

 More particularly, in this embodiment, the ports 1670 and 1672, which can include, for example, quick connectors, can engage with corresponding connectors 1674
20 and 1676, provided in a base unit 1678 of the photocosmetic device, in order to couple the heat exchanger to the base unit. Further, two lumens 1680 and 1682 extend from the base unit to a handpiece 1684 of the photocosmetic device, through an umbilical cord 1686, to provide passageways for circulating a cooling fluid, such as water, between the base unit and the handpiece. The circulating fluid extracts waste heat generated by a
25 heated element disposed within the handpiece. Upon engagement of the heat exchanger 1664 with the base unit 1678, the cooling fluid flows from the lumen 1680, via the connector 1676 and the port 1670, into the heat exchanger 1664. The cooling fluid at a lower temperature exits the heat exchanger via the port 1672 and flows through the lumen 1682 to return to the handpiece for extract more heat from the light source.
30 Alternatively, the ports 1670 and 1672 may engage connectors in the handpiece of the photocosmetic device.

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Although in many embodiments of the invention, ice is employed as the phase change substance contained in the internal structures 1668, other materials can also be employed. Such materials can include, without limitation, various frozen solutions of water and selected additives, such as alcohol or salt, pure alcohol or any other suitable material. In all such cases, the fluid filling the heat exchanger's housing external to the structures 1668 should exhibit a freezing temperature that is lower than the phase transition temperature of the phase change material. In some embodiments, the structures 1668 can be partially filled with a liquid having a vaporization temperature that is above the room temperature but below the cooling temperature.

Further, in some embodiments, rather than utilizing the latent heat associated with melting of a phase change material for extracting heat from a cooling fluid circulating through the heat exchanger, the heat of sublimation of a material, such as dry ice, contained within the structures 1668 is utilized.

In other embodiments, the ambient pressure in the structures 1668 is lowered below the atmospheric pressure by partial evacuation of air from the structures so as to raise the phase transition temperature associated with a phase change material confined within the structures.

As discussed above, it is generally preferable to design the internal structures 1668 so as to maximize their surface to volume ratios. To this end, in some embodiments of the invention, the external surface of at least some of the structures 1668 exhibit a textured pattern to maximize the surface area that is in thermal contact with a cooling fluid flowing through the heat exchanger. The texturing of the surface can be accomplished, for example, by providing semispheres, cylinders, or pyramids projecting from the surface.

The heat exchanger 1664 can be prepared for use by employing a variety of different approaches. For example, the heat exchanger can be placed in a freezer for a selected duration to cause the phase transition of a phase change material disposed in the structures 1668 from a liquid phase to a solid phase, e.g., ice can be generated by freezing water contained in the structures 1668. Alternatively, the heat exchanger can be coupled to a TE cooler, or any conventional refrigeration mechanism, which can be provided in the base unit 1670 or in a separate stand-alone unit, to cool the heat exchanger.

With reference to FIG. 17, in another embodiment of the invention, a phase change material, such as ice, is provided within a cassette 1788 that can couple to a base unit 1790 of a photocosmetic device so as to bring the phase change material into contact with a heat exchanger within the base. As described in more detail below, the heat exchanger can include passageways for flow of a cooling fluid, e.g., water, that circulates between the base unit and a handpiece of the photocosmetic device in order to cool a heated element incorporated in the handpiece. Alternatively, the cassette 1788 may couple to the handpiece of a photocosmetic device.

More particularly, with reference to FIG. 18A and FIG. 18B, the cassette 1888 can engage with a receiving module 1892, disposed within the base unit, in which a heat exchanger 1894 is incorporated.

FIG. 19 schematically illustrates various components of the exemplary cassette 1988 suitable for use in this embodiment of the invention. The illustrative cassette 1988 includes a housing 1996 in which a container (pouch) 1998 for storing a selected quantity of a phase change material is disposed. The container 1998 can be formed of a compliant material, such as plastic, having preferably good thermal conductivity. In this exemplary embodiment, the container 1998 includes a lower portion 1998a and an upper portion 1998b that surround two movable plates 19100 and 19102, which can move in a direction A to exert pressure on either the lower or the upper portions of the container 1998.

As shown in FIG. 18B and FIG. 19, prior to engagement of the cassette with the receiving module 1892, the pouch 1998 contains a selected quantity of ice, or other suitable material, while the upper portion of the pouch is empty. During formation of the ice in the pouch by freezing a selected quantity of water, the movable plate 19100 and a lower surface 1996a of the cassette's housing form a "mold" for generating a "brick" of ice while the movable plate 19102 squeezes the upper portion of the pouch to force any water remaining in the that portion to be transferred into the lower portion.

With reference to FIG. 20, upon engagement of the cassette with the receiving module 2092, the ice block contained within the pouch 2098 will be in thermal contact with the heat exchanger 2094. The heat exchanger includes an ingress port 20104 through which a cooling fluid that has extracted heat from the heated element, disposed in the device's handpiece, flows into the heat exchanger. The thermal contact of the

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lower portion of the pouch 2098 with the heat exchanger causes the heat carried by the cooling fluid to be transferred to the ice contained within the pouch 2098, thereby causing it to melt. In other words, melting of the ice provides the mechanism for removing heat from the cooling fluid, thereby lowering its temperature. Meanwhile, the movable plates 20100 and 20102 apply pressure to the lower portion of the pouch in order to maintain good thermal contact between the pouch and the heat exchanger, and further to force water generated as a result of melting of the ice into the upper portion of the pouch.

Hence, as the cooling fluid flows through the internal passageways of the heat exchanger, it gives up heat to the ice in the pouch 2098, and it finally exits the heat exchanger at a lower temperature through an egress port 20106. The cooling fluid is then returned to the handpiece in order to extract heat from the heated element.

As shown in FIG. 21, as the ice melts, the volume of the ice within the lower portion 2198a of the pouch 2198 decreases while water continues to accumulate in the upper portion 2198b of the pouch. Finally, as shown in FIG. 22, the ice is used up and the generated water is collected in the upper portion of the pouch. The cassette can then be removed from the base unit. As the cassette is pulled out of the base unit, the plate 22102 applies a pressure to the upper portion of the pouch to cause transfer of the collected water into the pouch's lower portion. Hence, when the cassette is fully disengaged from the base unit, the water is accumulated in the lower portion, as shown previously in FIG. 19.

The formation of ice in the cassette can be accomplished by employing a number of different techniques. For example, a TE cooler can be provided in the base unit to which the cassette can couple in order to freeze water contained in the pouch. Alternatively, such a TE cooler can be provided in a separate accessory unit. In another approach, the cassette can be placed in a freezer for a selected time period to freeze water contained in the pouch into ice.

In other aspects, the invention provides a cooling device that can be coupled to an optical transmissive element of the optics assembly of a handpiece of a photocosmetic device to remove heat therefrom. As shown in FIG. 23, in an exemplary embodiment, a cooling device 23108, herein also referred to as a heat exchanger, can surround the transmissive element 2336 to extract heat therefrom. The cooling of the

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transmissive element 2336 can in turn cause removing heat from (i.e., cooling) a portion of a patient's skin, which is in contact with a surface of the transmissive element during operation of the photocosmetic device, to ensure that the temperature of the treatment area remains within an acceptable range.

In one embodiment, the exemplary heat exchanger 23108 can be configured as a hollow sleeve that wraps around the transmissive element 2336 so as to be in thermal contact therewith. The sleeve, which is preferably formed of a thermally conductive material (e.g., copper), can contain a phase change material, such as ice or a vaporizable liquid, whose phase transition can be utilized in order to remove heat from the optical transmissive element. Preferably, the optical transmissive element is maintained at a temperature less than about 30°C. In addition, the sleeve can also be configured to directly remove heat from treated skin surface during operation of the photocosmetic device. Without any loss of generality, in the following description, the phase change material is assumed to be ice with the understanding that any other suitable phase change material can also be utilized. For example, in some embodiments, a frozen mixture of water and an additive, such as salt or alcohol, can be stored in the hollow sleeve.

Upon melting of the ice contained within the sleeve 23108, the generated water can be either released from the hollow sleeve onto the treatment area of the patient's skin or can be retained within the hollow sleeve. In some embodiments, the sleeve 23108 includes a plurality of openings, such as openings 23110, that allow introducing the water onto the treatment area. In other embodiments, therapeutic, cosmetic or cleaning agents can be added to the water to be also released onto the treatment area. Non-limiting examples of such additives include lotions, vitamins, aloe vera, petroleum jelly, oils, bee pollen, glycerin, moisturizers, preservatives, plant extracts, and fruit extracts. The openings can also be utilized for replenishing the phase change material in liquid form.

As discussed above, the hollow sleeve is preferably formed from a thermally conductive material, such as thermoconductive plastics or composite materials, ceramics, or metals. In some embodiments, the hollow sleeve can be formed of a semi-permeable or porous material such that, upon melting of the ice, the generated water can be selectively released onto the subject's treatment area. The pores can be configured to

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be sufficiently small such that the phase change material is dispersed onto the subject area only when in liquid form. Dispersal of the liquid can be controlled through the application of pressure, for example, during the movement of the transmissive element along the treatment area. More particularly, in some embodiments, a mechanism can be coupled to the sleeve to allow exerting pressure thereon as the transmissive element moves over the treatment area to facilitate introduction of the water and/or water mixed with therapeutic agents onto the skin.

It is generally preferable to design the hollow sleeve so that its surface to volume ratio is maximized. For example, the hollow sleeve can be designed to substantially cover a peripheral outer surface area, i.e., the surface area other than the area facing the patient's skin, of the transmissive element. Alternatively, the hollow sleeve can be designed to substantially cover both the outer peripheral surface area of the transmissive element and/or partially cover the top face of the transmissive element (FIG. 24A), while still permitting optical radiation to be transmitted to the subject's treatment area. In another embodiment, the hollow sleeve can be designed to be in thermal contact not only with the transmissive element but also with the heat sink 2432 that is turn in thermal contact with a heated element (e.g., a light source) for removing heat therefrom (*See* FIG. 24B).

The hollow sleeve can be of various shapes. In general, the shape of the sleeve is complementary to that of the transmissive element to ensure good thermal contact therewith. For example, some suitable geometrical shapes for the hollow sleeve include, though are not limited to, a toroid having a circular, a rectangular, an oval or any other cross-sectional shape. The hollow sleeve can be configured to easily attach to and closely contact with the transmissive element. A number of mechanisms can be utilized to secure the hollow sleeve to the transmissive element and/or the heat sink. Non-limiting examples include: a) the hollow sleeve can be designed from a semi-elastic or elastic material that can slip over the transmissive element, forming a pressure fit with the transmissive element and/or the heat sink, b) the hollow sleeve can be hinged to the device such that the sleeve can clip onto the transmissive element and/or heat sink c) the hollow sleeve can have a cut-away portion that is complementary to a projection on the transmissive element.

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In some embodiments, the hollow sleeve is disposable while in other embodiments, it can be recycled. For example, the sleeve filled with water, or other suitable material, can be placed in a freezer to generate ice. Alternatively, a stand-alone unit or a unit coupled to the device can be provided to house the hollow sleeve during regeneration, i.e., a freezing device into which the hollow sleeve selectively fits. In another embodiment, an additional element, e.g., a catalyst, can be added to either the hollow sleeve or the phase change material to initiate the phase change. In yet another example, the hollow sleeve can be designed to contain an inner tube that can be selectively filled with a material capable of initiating the phase change.

The surfaces of the transmissive element that receive light from the light source and/or are illuminated by light reflected from the treatment site are preferably formed of a material having a low coefficient of absorption of light in order to minimize heating of these surfaces.

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IV. Safety Features

A. Markers

Aspects of the present invention are directed to providing safety feature to prevent misuse of the device. In one embodiment, the device is capable of detecting a treatment area. For example, in some applications, phototreatment devices are capable of being used only on the desired target area, i.e., a patient's tissue or skin, and not on other parts of the body (e.g., the eyes) thereby preventing potential injury to the user. Additionally, preventing use of a phototreatment device on an improper surface such as table, mirror, clothes, etc. may avoid damage to the device and injury to the user. According to embodiments of this aspect of the invention, a topical substance is deposited on a tissue to be treated and the topical substance or a marker within the topical substance is detected by a sensor in the phototreatment device so that the phototreatment device functions only if the topical substance or marker is detected, and preferably only if the topical substance or marker is determined to be on a tissue (e.g., skin). The topical substance and/or the markers may be detected, for example, using optical, electrical, magnetic, or acoustic detection techniques.

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Two exemplary types of optical markers are absorptive and fluorescent markers. In some embodiments, a mild eye irritant is added to a topical substance or the marker, to deter a user from applying the topical substance on an eye.

5 In some embodiments of optical systems for detecting an area of treatment, a topical substance is applied to a tissue, a detection source provides light at a wavelength absorbed by the topical substance or an optical marker within the topical substance, and a detector is configured and arranged to detect a reflected portion of said light (i.e., light that is not absorbed). Preferably, the wavelength detected is close to the peak of
10 absorption of the topical substance or optical marker, such that a reduction in the detected signal indicates the presence of the optical marker. In this embodiment, the optical detector is designed as a reflectometer to detect reflected light at a wavelength absorbed by the topical substance or optical marker.

Preferably, the topical substance or marker is characterized by an optical
15 absorption spectrum substantially different from that of skin, to facilitate detection. Also, preferably, the absorption band of the topical substance or marker is outside the working spectrum of the phototreatment device, such that detection of the marker may be achieved without interference from source. Preferably, the optical density of the topical substance or marker is higher than the optical density of the skin for the light
20 reflected from the patient's skin in the absorption band to facilitate detection of the topical substance or marker. The term "optical density" (OD) is defined herein to mean

$$OD = -\ln \frac{I_r}{I_i},$$

25 where I_i is the intensity of the incident light and I_r is the intensity of registered light.

FIG. 25A is a graphical representation of absorption spectra for some exemplary dyes suitable for use as markers of areas to be treated. The absorption spectra were taken using a UV spectrophotometer of dye solutions in glycerol with following concentrations: (1) 10 mg/ml Food Blue, (2) 1 mg/ml Toluidine Blue, (3) 1 mg/ml
30 Brilliant Green, (4) 1 mg/ml Indigo Carmine. FIG. 25B is a graphical representation of absorption spectra for some exemplary, biocompatible dyes (1: Fast Green, 2:

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Erioglaucine, 3: Methylene Blue, 4; Indocyanine Green) suitable for use as markers of areas to be treated.

As shown in FIGs. 25A and 25B, Food Blue, Toluidine Blue, Brilliant Green, Indigo Carmine, Fast Green, Erioglaucine, Methylene Blue, and Indocyanine Green can be used as absorptive markers in combination with a suitable source (e.g., a 550-870 nm diode laser or 550-870 nm lamp). In addition to the markers indicated in FIGs. 25A and 25B, another class of absorptive markers is non-organic absorbers (e.g., carbon particles; china ink; compounds containing ions of Cu, Fe, Au, Ag, and Zn).

In some embodiments of systems for detecting areas of treatment, the reflectance is at two substantially different wavelengths, λ_1 and λ_2 , where λ_1 lies within the absorption band of the topical substance or marker and λ_2 lies outside the absorption band. In such embodiments, a determination that a topical substance is located on a tissue may be determined when two conditions are fulfilled:

15

$$R_{\min} < R_2 < R_{\max},$$

$$\frac{R_1}{R_2} < A_t,$$

where R_1 and R_2 are the reflectance coefficients measured at the wavelengths λ_1 and λ_2 , respectively; R_{\min} and R_{\max} are the minimal and maximal threshold values of the reflectance coefficients at wavelength λ_2 , respectively; and A_t is a threshold value of the reflectance ratio. Preferably, R_{\min} and R_{\max} are chosen to correspond to the physiological range of skin reflectance for λ_2 . The above recognition algorithm is merely exemplary, and any other suitable detection algorithm may be used.

It is to be appreciated that if the peak of absorption shifts when the topical substance and/or marker is applied to or penetrates into the skin, the wavelength to be detected may be adjusted in such a way as to correspond to the shifted absorption peak. Such shifts may be used to provide additional assurance that the topical substance or marker has indeed been applied to skin.

As mentioned above, optical detection of an area to be treated may include a fluorescent marker. The term "fluorescence" is defined herein to encompass all types of non-elastic re-emission of electromagnetic energy, including (but not limited to)

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luminescence and Raman scattering. A “fluorescent marker” is any substance having at least one active ingredient characterized by fluorescence excitation.

Preferably, a fluorescent marker has an emission spectrum substantially different
5 from that of skin. Also, preferably the fluorescent marker has a high quantum yield of fluorescence. Preferably, biocompatible fluorescent color additives are used as fluorescent markers. For example, suitable markers include Eosin Y; D&C Orange Nos. 5, 10, and 11; D&C Red Nos. 21, 22, 27, and 28; and Zinc sulfide.

In order to detect a fluorescent marker, a detection source is configured and
10 arranged to provide light in the absorption band of the fluorescent marker, and a detector is configured and arranged to detect light emitted by the fluorescent marker. For example, the device may be a fluorimeter. In some embodiments, the fluorescent marker is illuminated with wavelength of light λ_1 which lies within the excitation band of the fluorescent marker, a resulting fluorescent signal is measured at wavelength λ_2 in
15 the emission band of the fluorescent marker. In such embodiments, positive identification occurs when the following condition is fulfilled:

$$I_{12} > F_t,$$

20 where F_t is a threshold value of the fluorescent signal. Other detection algorithms can be devised by those skilled in the art without departure from the scope of the present invention.

If one or both of the excitation band and emission band shifts when the optical marker is applied to or penetrates into the skin, the wavelengths λ_1 and λ_2 can be
25 adjusted in such a way as to correspond to the shifted bands. A shift of a wavelength may be used to provide information related to the nature of the substrate (e.g., is the substrate skin or non-skin).

As indicated above, the topical substance or a marker within the topical substance may be detected through an electrical detector. For example, the topical
30 substance or marker may have electrical conductivity (preferably, more than two-fold) higher than the maximal electrical conductivity of the skin. Examples of suitable topical substances or markers are conductive lotions and gels, such as: ALOE-STAT® CONDUCTIVE SKIN LOTION (Walter G Legge Company Inc), LECTRON 2

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CONDUCTIVITY GEL and ELECTRO-MIST ELECTROLYTE SPRAY

(Pharmaceutical Innovation), 3M CONDUCTIVE ELECTRODE GEL (3M Surgical Products Division). Some conductive lotions may penetrate into the skin. To detect an electrically conductive topical substance or marker, a phototreatment device may be equipped with a detector capable of detecting an electrical characteristic of the marker. For example, the detector may be a contact ohmmeter.

Also as indicated above, a topical substance or a marker within the topical substance may be detected through an acoustic detector. For example, a topical substance and/or marker may be designed to have an acoustical transmission resonance at a selected acoustic frequency, such that application of the topical substance and/or marker to the skin surface can change (e.g., dampen) the resonance of the topical substance and/or marker. In such embodiments, a phototreatment device may be equipped with an acoustic source (e.g., a piezo-electric crystal) and a transducer, such that a region covered with the topical substance and/or marker is identified when the acoustic signal exceeds a preset limit. For example, the detector may indicate that both of the following is true: 1) there is a signal at the resonance frequency (the film is present); and 2) said signal is dampened (i.e., the topical substance and/or marker is on a tissue).

As further indicated above, a topical substance or a marker within a topical substance may be detected through a magnetic detector. For example, the topical substance and/or marker may consist of or contain compounds with static or induced magnetic susceptibility. For example, magnetic microparticles, paramagnetic (FeO) and ferromagnetic (CrO₂, magnetite). Such compounds may be coated with a polymer (polystyrene) and, for example, the particles may have sizes of 3 - 10 μm (e.g., such a magnetic material is available from Spherotech, Inc.) or up to 1 μm (e.g., such a magnetic material is available from Polysciences, Inc). To minimize light absorption of magnetic particles in the working band of a phototreatment source, they can be coated by a highly reflecting metal such as Au, Ag, Cu, Al or by a multilayer dielectric coating (Colored Magnetic Particles).

According to another aspect of the invention, additives can be advantageously included in a topical substance. The additives may provide a variety of effects. The following is an exemplary list of possible cosmetic additives: mineral oil, petrolatum,

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capric/caprylic triglyceraldehydes, cholesterol, lanolin, dimethicone/cyclomethicone, almond oil, jojoba oil, avocado oil, sesame oil, sunflower oil, coconut oil, grapeseed oil, glycerin (glycerol), propylene glycol, sorbitol, hyaluronic acid, lecithin, Urea, lactic acid, pyrrolidone carboxylic acid (NA-PCA), phospholipids, collagen, elastin, ceramide, vitamins A,B,C,D,E,K, hyaluronic acid, retinol, potassium hydroxide, or thioglycolic acid.

Some additives interact synergistically with the phototreatment wavelength or wavelengths of light. Three exemplary mechanisms may be involved in the synergistic action of the device and the additives. First, the device may create a controlled profile of elevated temperature in skin, such that the transdermal penetration of the additive may be facilitated, and a higher concentration of an active compound(s) in the target area may be achieved. Second, a mild hyperthermia at the target site may increase the efficiency of an active ingredient(s) and, thus, enhance the desired effect. Third, an additive may be activated photochemically by the light emission of the device.

FIG. 4 illustrates photo-enhancement of transcutaneous penetration of a retinol-containing preparation observed in *in vitro* conditions. Light with a wavelength of 800-2000 nm and flux 0.5 W/cm^2 was used in this experiment. The relative concentration of retinol, the active ingredient in the solution, after 30 minutes exposure to light was measured using UV absorbance. As shown in FIG. 26, the concentration of retinol is greatest when exposed to light.

B. Speed of the Device

Another aspect of the present invention is a motion sensor for determining the scanning speed of a phototreatment device. For example, an optical, electrical or magnetic marker may be used for detecting motion and/or determining scanning speed.

FIG. 27 is a schematic view of one example of a system 2700 for measuring a speed of motion S of a phototreatment device over a tissue 27150 using a topical substance or a marker 2710 added to a topical substance.

System 2700 may be located on a head of a phototreatment device such that as the head is moved across a patient's tissue 27150, the speed of motion S can be monitored. System 2700 comprises an applicator 2720 for applying a layer 2725 comprising topical substance and/or marker, and a detector system 2750 to detect a

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signal generated by layer 2725. As described below, the signal may be optical, electronic, or magnetic.

5 A detector system 2750 comprises a detector 2750 and suitable electronics to detect the signal generated by or in response to the layer 2725 and determine the speed of motion S at which the head is moving across tissue 27150. For example, the calculated speed may be used to control the fluence, wavelength(s) or pulse width of the light source, to control the application of a consumable substance, for display of speed S, or any other any other purposes. Further discussion of uses for a measured speed of
10 motion S are given in U.S. Application 10/154,756, incorporated by reference herein above.

Applicator 2720 is located to deposit layer 2725 onto tissue 27150. Applicator 2720 may be any known applicator capable of depositing a layer of material on a tissue. In some embodiments, applicator 2720 deposits a layer of uniform thickness.

15 The topical substance and marker may be any suitable materials capable of generating or responding to a suitable signal (e.g., optical, electrical or magnetic signal). In some embodiments, the material has a low enough viscosity to allow the material to be deposited by applicator 2720, and high enough viscosity, such that it remains on the tissue after deposit. Preferably, the material is easily removed by water and/or soap and
20 water. Preferably, the topical substance and/or marker is index-matched to tissue 27150 to improve optical coupling of light from a source to the tissue (i.e., light from source 125 in FIG. 1A above) into tissue 27150.

In some embodiments, the topical substance and/or marker is a fluorescent material. Examples of appropriate fluorescent materials include those described above
25 for use with consumable substances. Preferably the absorption band of the fluorescent material does not overlap with the wavelengths over which source 125 emits, to prevent interference.

Layer 2725 may be deposited using applicator 2720; however, in some
30 embodiments of the invention, fluorescent topical substance and/or marker is applied by hand to form layer 2725; in such embodiments applicator 2720 may be omitted. In some embodiments, a fluorescent topical substance and/or marker is selected such that after applying the fluorescent topical substance and/or marker (e.g., by hand or any other suitable mechanism) and allowing it to remain for a predetermined time (e.g., 1-5

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minutes), the fluorescent topical substance and/or marker may be removed as some of the fluorescent topical substance and/or marker will have penetrated the skin and still be detectable.

5 In some embodiments, a light projector 2730 projects a plurality of pulses of light onto layer 2725 having a wavelength in the absorption band of the fluorescent material to cause the fluorescent material to generate fluorescent light (i.e., to fluoresce). Light projector 2730 may be any LED, laser, lamp or any other known source of light capable of causing layer 2725 to generate fluorescent light. In some embodiments, the
10 light pulses are uniform in intensity to generate uniform amounts of fluorescent light, and/or the pulses are generated at uniform intervals of time. Alternatively, the light may have any selected signal such that the signal has a known intensity (e.g., the signal may be a harmonic signal of known amplitude). Light projector 2730 may consist of a light source or may comprise a light source and focusing optics, beam steering optics, or any
15 other suitable optical components.

 In embodiments where the topical substance and/or marker is a fluorescent marker, detector 2740 is located to receive fluorescent light. Detector 2740 may be any detector sensitive to the fluorescent light emitted by fluorescent layer 2725 after light is projected onto it by the light projector 2730. Preferably, detector 2740 is a low electrical
20 noise detector.

 In some embodiments, detector 2740 is a known distance L from light projector 2730. Detector 2740 may measure an intensity using a single photosensitive element to determine the location of a peak intensity of the fluorescent light, or may have an array of photosensitive elements to determine the location of the peak intensity of the
25 fluorescent light. In some embodiments, a band pass filter 2742 may be placed in front of detector 2740 to filter any extraneous light (i.e., any light other than fluorescent light emitted by fluorescent layer 2725).

 Detector system 2750 is coupled to detector 2740 to calculate the speed of motion S. Speed of motion S may be calculated using any known method. In some
30 embodiments, light projector 2730 projects pulses onto layer 2725, which are uniformly spaced in time, and detector system 2750 determines a time interval between peaks in the fluorescent light intensity as detected by detector 2740. By calculating a ratio of the distance L and the time interval between the peaks, speed of motion S may be

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determined. Alternatively, light projector 2730 may project pulses of light of known intensity, and the detector system 2750 measures the intensity of the peak detected by the detector 2740. If light projector 2730 generates a pulse of light having a known
5 intensity and if fluorescent layer 2725 emits fluorescent light having a known intensity and a known decay rate, a time interval between the pulse of light produced by projector 2730 and time at which detector 2740 detects the light can be calculated. Because there is a known distance L between light projector 2730 and detector 2740, by calculating a ratio between distance L and time interval, a speed can be calculated.

10 In other embodiments, the detector 2740 need not be a known distance L from light projector 2730. Instead, the applicator deposits bands of fluorescent marker in a known pattern, having a known spacing. Accordingly, light projected onto the pattern by projector 2730 is modulated by the known pattern, so the speed can be calculated. For example, the known pattern may be formed by fluorescing molecules or particles at
15 periodical parallel lines (bars) with period Δ . When the handpiece is moved across the skin, the reflection signal is modulated with a period $P=\Delta/S$, so the speed can be calculated as $S=\Delta/P$.

In other embodiments of system 2700, layer 2725 is a topical substance and/or marker that is absorptive of light from projector 2730. In such embodiments, projector
20 2730 provides light having a wavelength in the band of absorption of the absorptive layer 2725. Similar to the fluorescent layer system described above, projector 2730 may be a projector that provides periodic pulses or harmonics; however, in the present embodiment, detector 2750 may measure a reflected portion of light, or may measure heat generated by the absorption of light by the layer (e.g., the detector may be an
25 infrared detector, a thermocouple, or a thermistor). Similar to the fluorescent topical system and/or marker system described above, the speed can be determined by measuring the time between pulses or using a known marker pattern.

In addition to optical topical substance and/or markers, electrical topical substance and/or markers may be used to measure speed of a phototreatment device. For
30 example, a Hall sensor can be used as a motion sensor to detect magnetic field from the current flowing through the topical substance and/or marker. Current and voltage in the Hall sensor will be proportional to the current through the topical substance and to speed of motion S. Alternatively, a conductive pattern can be formed on the film as periodical

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conductive lines (bars). Using an electrical sensor (e.g., an ohmmeter), speed S can be determined as a ratio of the spatial period of the conductive pattern to the period of modulation of the signal from the ohmmeter.

5 Alternatively, a magnetic topical substance and/or marker may be used for measuring speed of a phototreatment device. Movement of the topical substance in the magnetic field can be detected as electromotive force in simple voltage sensor. A magnetic pattern can be formed on the film, for example, a pattern comprised of periodic magnetic lines (bars). In such embodiments, the electromotive force in the voltage
10 sensor will be modulated with a period inversely proportional to speed S.

C. Visualizing the Treated Area

FIG. 28 is a schematic illustration of another aspect of the present invention directed to visibly indicating an area that has been treated. Because treatment with a
15 phototreatment device 2800 usually does not cause any visible change to the skin, a topical substance and/or marker 2810 may be deposited to provide a visual indication of areas that have been treated.

 In some embodiments, a topical substance 2810 and/or marker having optical characteristics that are visible to an operator of the phototreatment device are deposited
20 by an applicator coupled to the phototreatment device 2804. The applicator 2820 deposits the substance 2810 onto the tissue 2805 as the device is moved over a tissue region 2805, but prior to irradiation of the tissue region 2805 by the radiation source 2830 of the phototreatment device 2804. For example, the topical substance and/or
25 marker 2810 can be comprised of a layer of lotion, gel, an adhesive wax, or a dye described above with reference to FIG. 25A and FIG. 25B may be used.

 Alternatively, the topical substance and/or marker may be deposited by hand or any suitable device, and the topical substance and/or marker may be removed by the phototreatment device such that after the phototreatment device has passed over the tissue, the operator can visually discern the treated area. In some embodiments, the
30 topical substance and/or marker has one or more optical characteristic that change after treatment (i.e., after exposure to phototreatment light). For example, the topical substances and/or marker may be invisible prior to exposure to the treatment light and become visible after treatment, or the topical substances and/or marker may be visible

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before treatment and become invisible after treatment (e.g., the topical substances and/or marker may be photo or thermally bleached). For example, suitable dyes can be selected from the polymethine, coumarine, or xanthene groups.

5 It is to be appreciated that although the aspects of the invention described in this application were described for use with a phototreatment device, aspects of the invention may have application in other types of devices that use consumable substances. Additionally, it is to be appreciated that, although consumable substances have been described as having been delivered through a replaceable container integrated with or
10 attached to a phototreatment device, the consumable substances may be held within containers that are not non-integrated with and non-attached to a phototreatment device; in such embodiments consumable contents from a container may be directly applied to a tissue without passing through a phototreatment device.

15 **D. Shut-Off Mechanism**

40. In yet another aspect, the invention provides a system, having a radiation source, detector, and processor, for measuring a speed of motion of a phototreatment device over a tissue region, where the phototreatment device has an electromagnetic source to effect a phototreatment and the tissue region has a substance applied thereto. An
20 applicator coupled to the phototreatment device can be used for depositing the substance onto the tissue prior to irradiation of the tissue region by the radiation source. The substance contains a marker. Non-limiting examples of markers include fluorescent markers, absorptive markers, electrical markers, optical markers, and magnetic markers. The radiation source is positioned on the phototreatment device to irradiate the tissue
25 region and the applied substance. The detector is associated with the phototherapeutic device configured and arranged to monitor the substance. The processor calculates a speed of motion of the phototreatment device based on signals from the detector. The radiation source can be further coupled to the phototreatment device for irradiating a plurality of tissue locations and the substance is applied thereto as the device moves over
30 the tissue region. The detector can be further coupled to the phototreatment device at a selected distance from the radiation source and arranged to monitor a response of the substance at an irradiated location subsequent to said irradiation. The processor can be

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further coupled to the detector for comparing said monitored response with a pre-selected value to determine a speed of motion of said phototreatment device.

5 The system can contain a comparator, for comparing the calculated speed of motion with a defined maximum speed value in order to determine when the calculated speed has exceeded a threshold established by the defined maximum speed. A preferred maximum speed in the 100-500 mm/sec range. A comparator can also be used for comparing the calculated speed of motion with a defined minimum speed value in order to determine when the calculated speed has fallen below a threshold established by the
10 defined minimum speed. A preferred minimum speed is in the 10-100 mm/sec range. The system also contains a shut-off switch responsive to a control signal to terminate phototreatment when the speed has fallen below the threshold, thereby preventing injury to the user. For example, the control signal can enable the processor to control the electromagnetic source based on the speed of the phototherapeutic device. The shut-off
15 switch can include a shutter that blocks the radiation and/or an alarm to alert the user.

Those skilled in the art will appreciate, or be able to ascertain using no more than routine experimentation, further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims.
20 All publications and references are herein expressly incorporated by reference in their entirety.

CLAIMS:

1. A container, comprising:
5 a container housing defining at least one compartment therein;
a substance contained in the compartment, the housing and the compartment
being capable of coupling to a phototreatment device to permit heat transfer between the
substance and the device; and
an indicator coupled to the compartment.
10
2. The container of claim 1, wherein the substance is a re-useable substance.
3. The container of claims 1 or 2, wherein the substance is a phase change material.
- 15 4. The container of claim 3, wherein the phase change material is selected from the
group consisting of liquid carbon tetrafluoride, liquid CO₂, ice, frozen lotions, frozen
creams and frozen gels.
5. The container of claim 3 or 4, wherein the phase change material exhibits a phase
20 transition from a liquid to a gaseous state.
6. The container of claim 3 or 4, wherein the phase change material exhibits a phase
transition from a solid to a liquid state.
- 25 7. The container of claim 1, 3, 4, 5, or 6, wherein the substance is a consumable
substance.
8. The subassembly of claim 7, wherein the consumable substance is chosen from
the group consisting of a topical substance, a coolant, a super-cooled liquid, a
30 pressurized gas, and a phase change material.

- 60 -

9. The container of claims 1 or 3-8 wherein the housing and compartment are capable of being coupled to a phototreatment device to provide a flow path for substance release during phototreatment.

5

10. The container of any one of the preceding claims, wherein the substance further comprises a marker.

10

11. The container of claim 10, wherein the marker is selected from the group consisting of absorptive markers, photoactive markers, optical markers, fluorescent markers, electric markers, and magnetic markers.

15

12. The container of claim 10, wherein the marker indicates an aspect of the substance.

20

13. The container of claim 10, wherein the marker is selected from the group consisting of dyes, metals, ions, colored particles, photosensitive dyes, photosensitive materials, carbon particles, conductive skin lotions, electrolyte sprays, conductive electrode gels, and oxides.

25

14. The container of any one of the preceding claims, wherein the compartment is capable of being fluidly coupled to at least one of a head of a phototreatment device, a heat dissipating element, target area, or a tissue to be treated.

15. The container of any one of the preceding claims, wherein the at least one compartment further comprises a first compartment and a second compartment, the first compartment adapted to couple to a tissue, and the second compartment adapted to couple to a heat dissipating element in the phototreatment device.

30

16. The container of claim 15, wherein the first compartment contains a topical substance

- 61 -

17. The container of claim 16, wherein the topical substance comprises at least one of lotions, creams, waxes, films, water, alcohols, oils, gels, powders, aerosols, and granular particles.

5

18. The container of claim 16 or 17, wherein the topical substance is a substance to achieve at least one of moisturizing skin, UV protection, tanning skin, improving skin texture, improving skin tone, reduction and/or prevention of cellulite, reduction and/or prevention of acne, wrinkle reduction and/or prevention of wrinkles, reduction of scars, reduction and/or prevention of vascular lesions, reduction in pore size, oil reduction in sebum secretion, skin elasticity improvement, reduction in sweat secretion, reduction and/or improvement of odor, body hair reduction or removal, and stimulation of hair growth.

10

15

19. The container of claim 15, wherein the second compartment contains a coolant.

20. The container of claim 19, wherein the coolant is one of liquid tetrafluorethane (R-134a), liquid CO₂, ice, frozen lotion, frozen gel, cristallohydrates (45%CaCl*6H₂O: 55%CaBr*6H₂O ore KF*4H₂O), organic materials as HO(C₂H₄O)₈C₂H₄OH (PE Glycol), Caprilic acid, Hexadecane, and Paraffin 5913.

20

21. The container of any one of the preceding claims, wherein the indicator is selected from the group consisting of mechanical indicia, optical indicia, magnetic indicia, electronic indicia, and piezoelectronic indicia.

25

22. The container of any one of the preceding claims, wherein the indicator indicates an aspect of the container.

23. The container of any one of the preceding claims, wherein the indicator indicates an aspect of the substance.

30

24. The container of any one of the preceding claims, wherein the indicator is coupled to a detector that is configured and arranged to monitor a substance parameter.

- 62 -

25. The container of claim 24, wherein the detector is selected from the group consisting of a mechanical detector, an optical detector, a magnetic detector, an
5 electronic detector, and a piezoelectronic detector.

26. The container of any one of the preceding claims, wherein the container is further coupled to a phototreatment device, such that the container is user-replaceable.

10 27. A method of operating the phototreatment device of claim 26 comprising:
coupling the container of an adjuvant substance to the phototreatment
device, the container having at least one indicator associated therewith to permit
monitoring of the substance;
evaluating the indicator; and
15 enabling operation of the phototreatment device if the evaluation is
acceptable.

28. A system for measuring a speed of motion of a phototreatment device over a
tissue region, the phototreatment device having an electromagnetic source to effect a
20 phototreatment and the tissue region having a substance applied thereto, comprising:
a radiation source positioned on the phototreatment device to irradiate the tissue region
and the applied substance;
a detector associated with the phototherapeutic device configured and arranged
to monitor the substance; and
25 a processor for calculating a speed of motion of the phototreatment device based
on signals from the detector.

- 63 -

29. A cooling system for extracting heat from a light generating device, comprising:
a heat exchanger in thermal contact with a cooling fluid that extracts heat from the light generating device, and
5 a phase change medium in thermal contact with said heat exchanger, said phase change medium absorbing heat from the heat exchanger to undergo a phase transition, thereby removing heat from the heat exchanger.
30. A cooling cartridge for coupling to a photocosmetic device, comprising
10 a housing for storing a phase change medium, said housing being adapted for coupling to a heat sink incorporated in said device so as to provide thermal contact between said phase change medium and said heat sink.
31. The cooling cartridge of claim 30, further comprising
15 one or more channels formed in said housing for removing fluid generated upon a phase transition of said phase change medium in response to absorbing heat from said heat sink.
32. A phototreatment device for use with a marker, comprising:
20 a radiation source to effect a phototreatment on a region of tissue; and
a detector assembly to detect the marker and to selectively activate the radiation source based on marker detection.
33. A cooling system for extracting heat from a handpiece of a photocosmetic
25 device, comprising:
a heat sink in thermal contact with a heated element in the handpiece to extract heat therefrom,
a cartridge storing a phase change medium, said cartridge being adapted for coupling to the heat sink so as to provide thermal contact between said phase change
30 medium and the heat sink, said phase change medium absorbing heat from the heat sink to undergo a phase transition from a solid state to a liquid state thereby removing heat from the heat sink,

- 64 -

wherein said cartridge includes one or more channels for removing liquid generated upon said phase transition.

- 5 34. A cooling system for extracting heat from a light generating device, comprising:
 a circulating cooling fluid in thermal contact with a heated element in
 said light generating device to remove heat therefrom;
 a cartridge containing a selected quantity of a phase change medium, said
 cartridge having an ingress port and an egress port and being adapted for removable and
10 replaceable placement in a flow path of said fluid to allow inflow of said fluid carrying
 heat from the heated element via said ingress port so as to provide thermal contact
 between said fluid and said phase change material.

35. A method of operating a phototreatment device, comprising:
15 applying a topical substance to a tissue;
 detecting a parameter associated with the topical substance; and
 enabling operation of the phototreatment device based on a detected
 value of the substance parameter.

Figure 1A

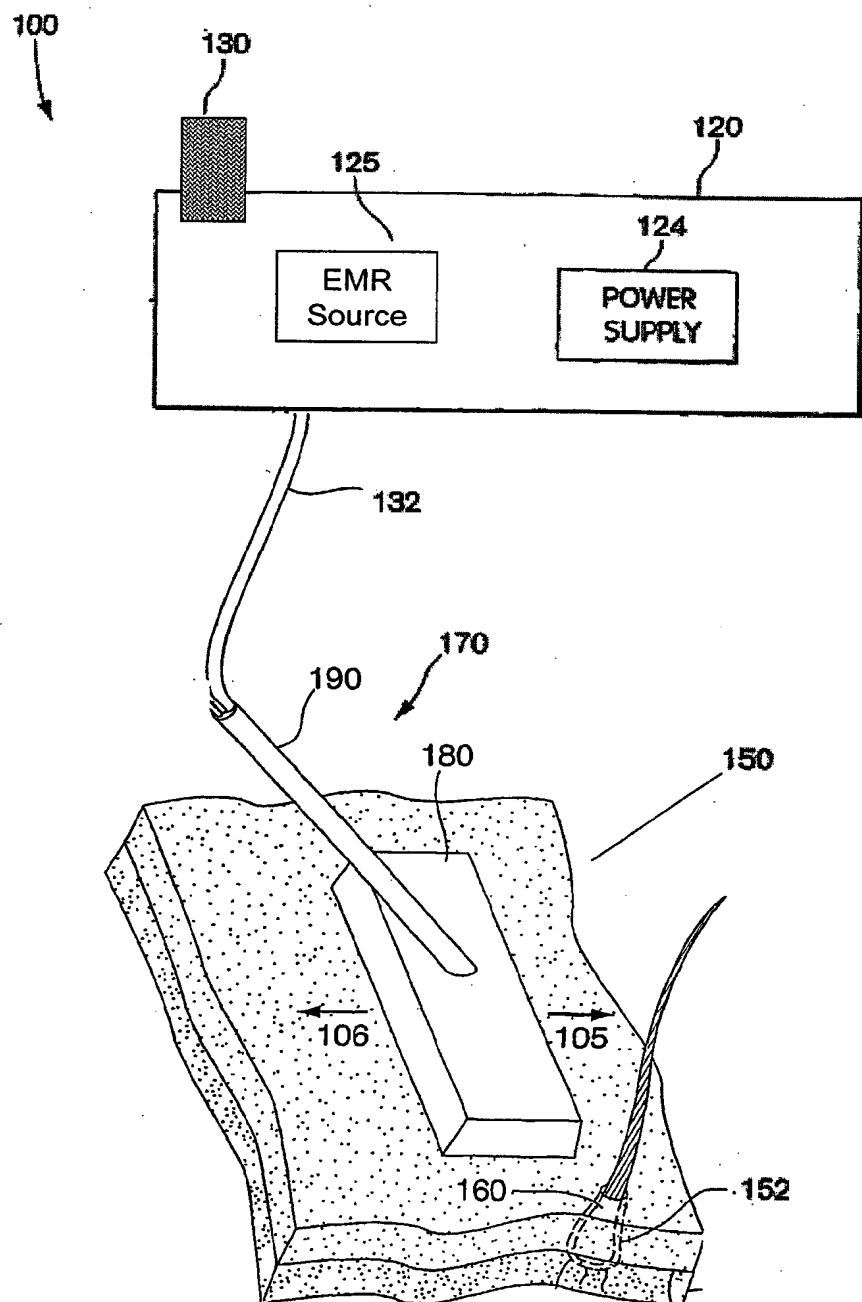
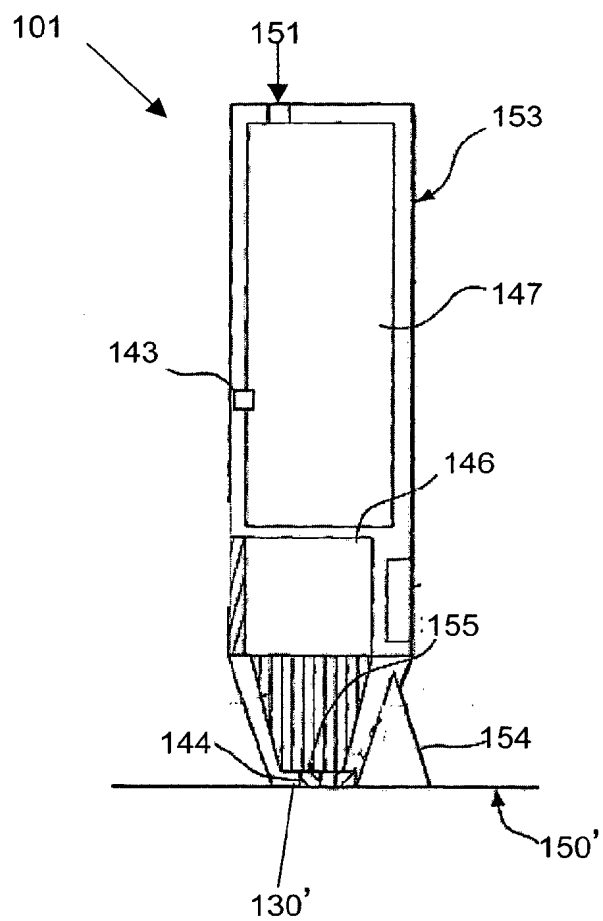
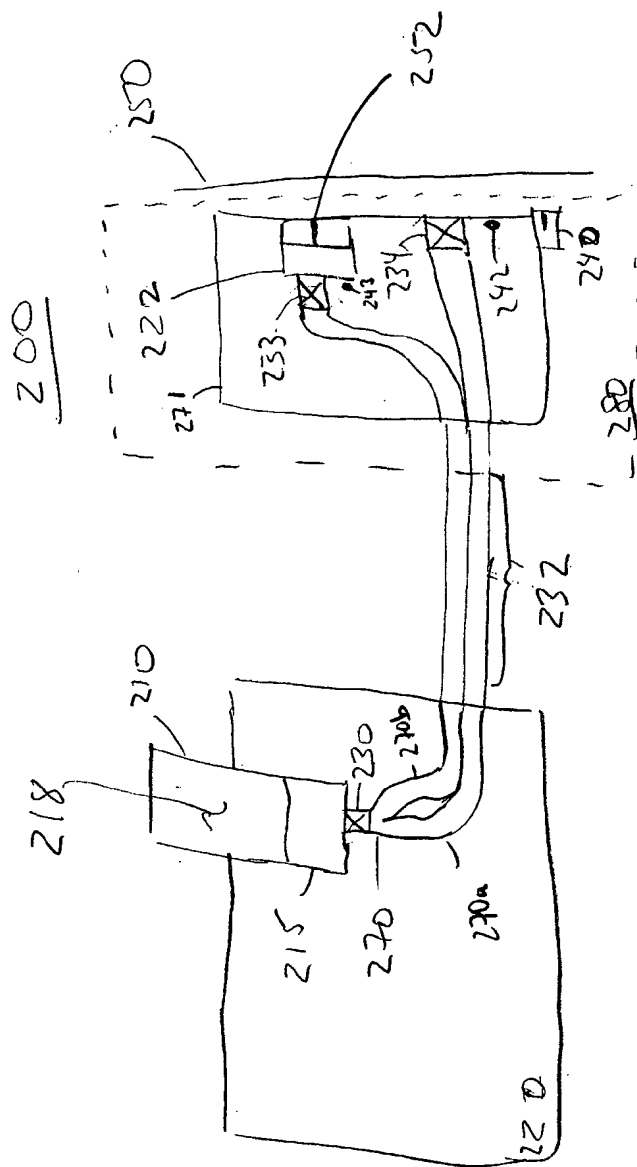


Figure 1B





26.2

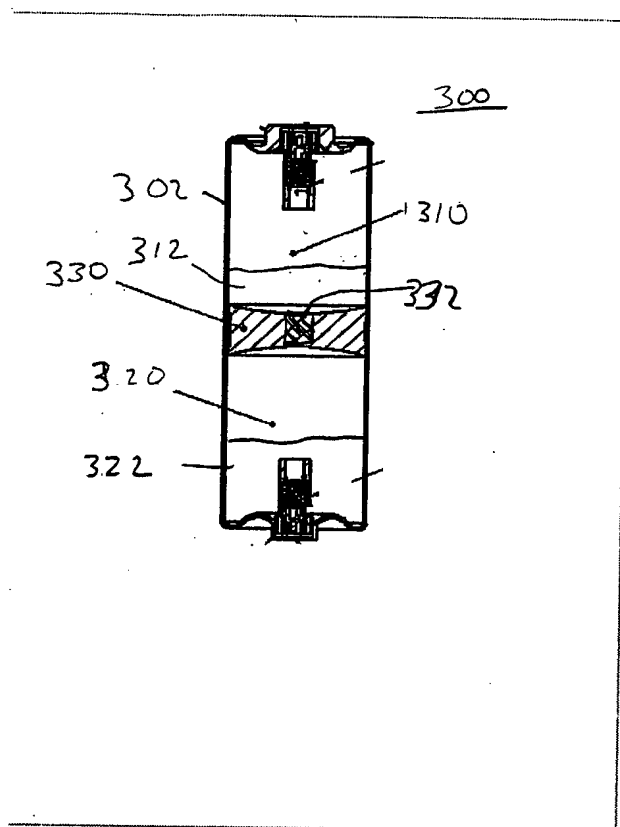


FIG. 3A

350

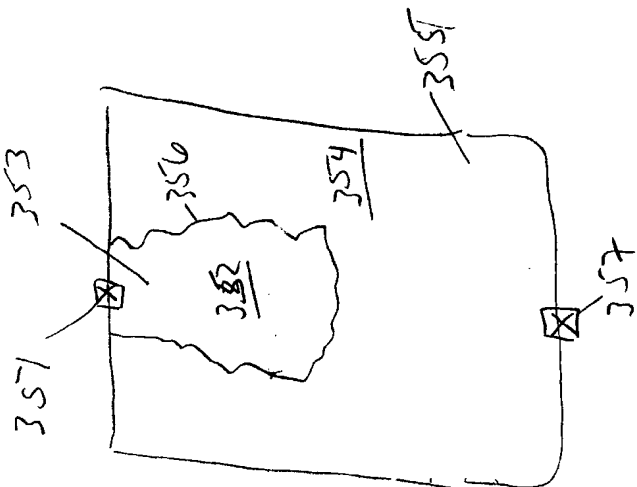


FIG 3C

340

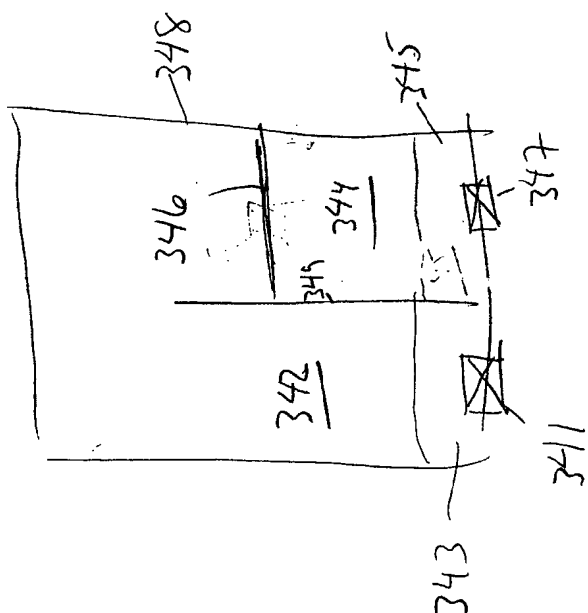
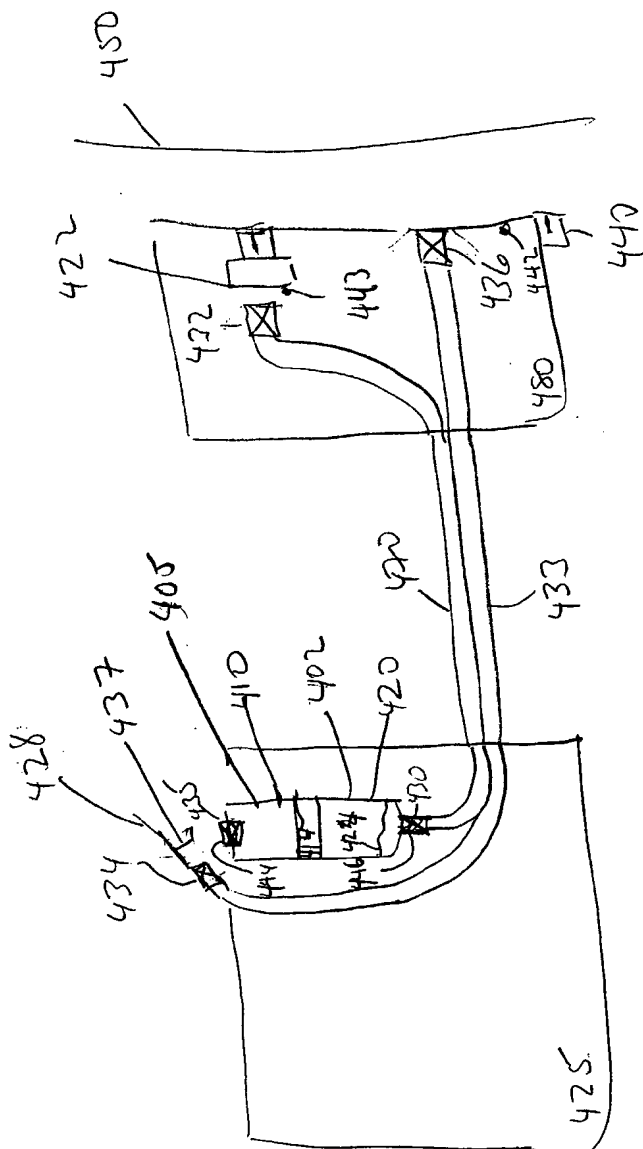


FIG 3B

400



4A

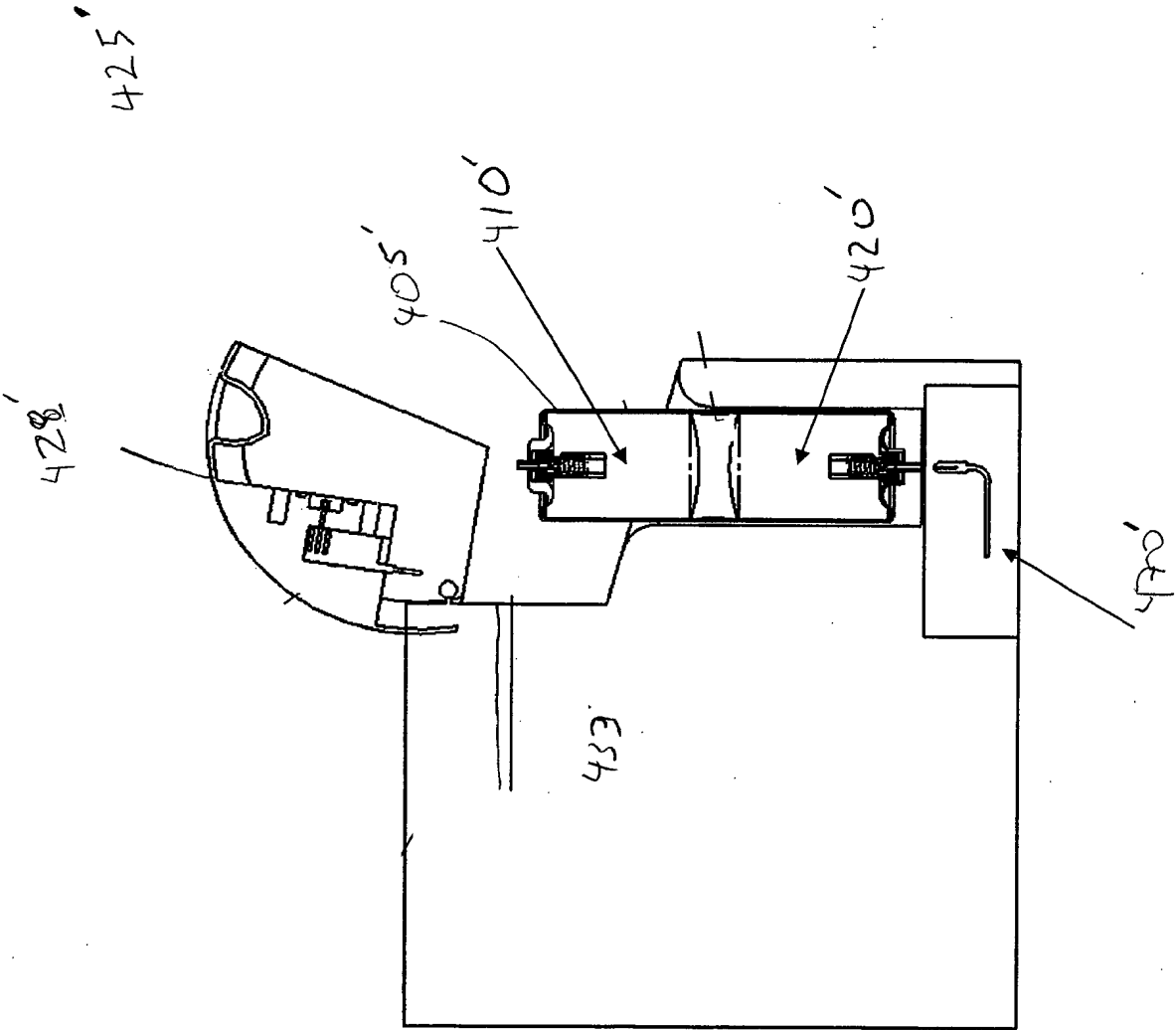
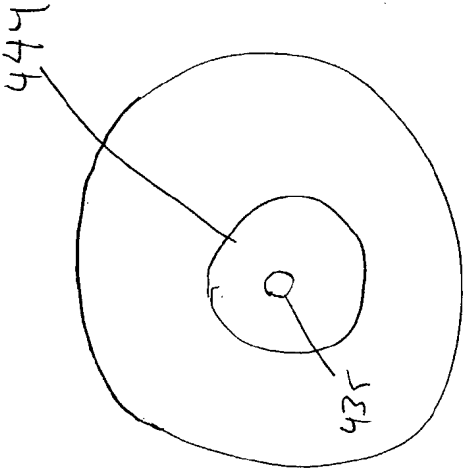


FIG. 4B

490



492

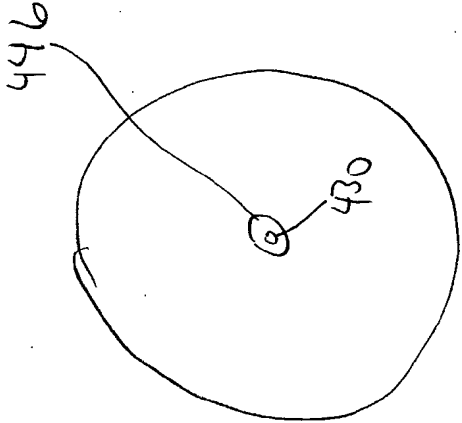


FIG. 4C

FIG. 4D

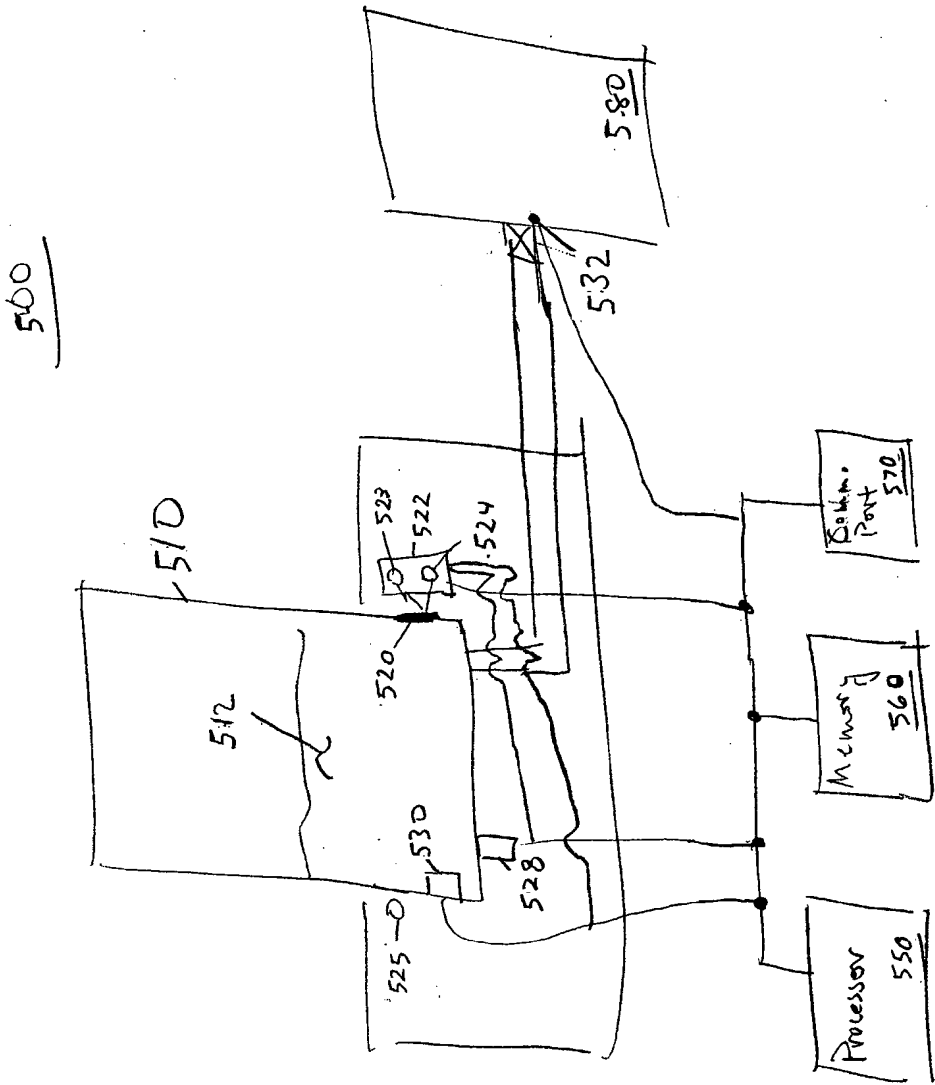


Figure 5A

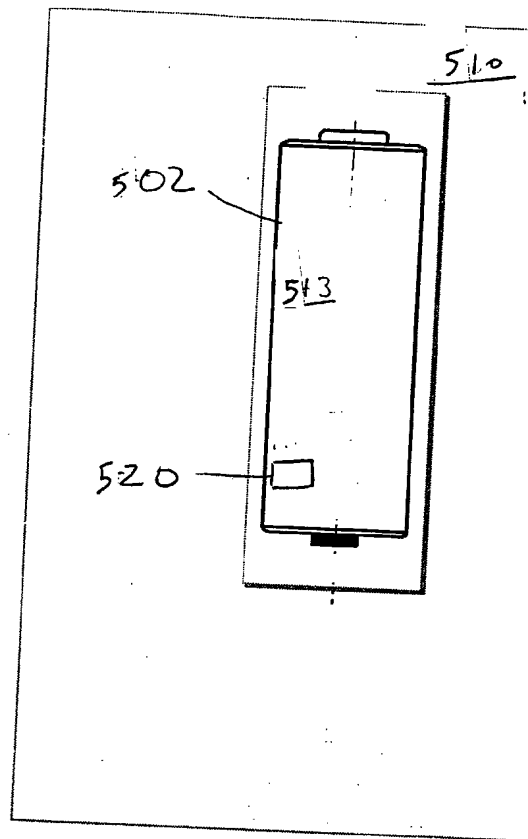


Figure 5B

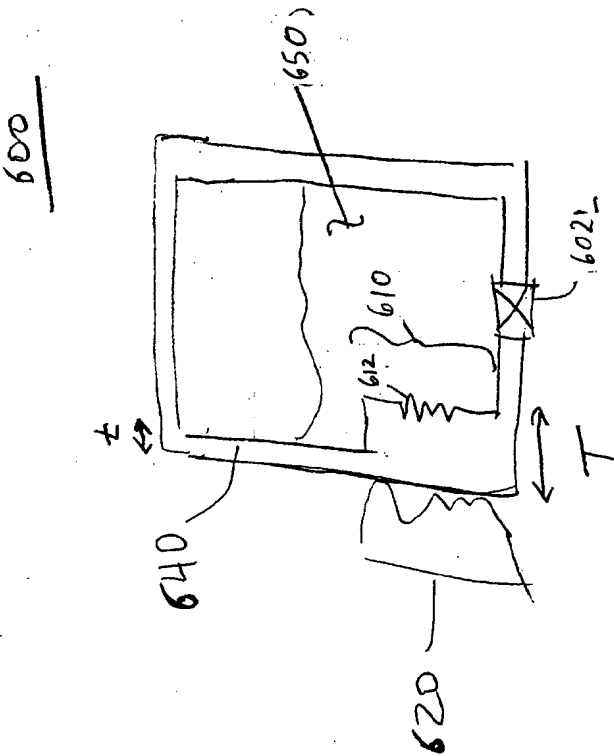


Figure 6

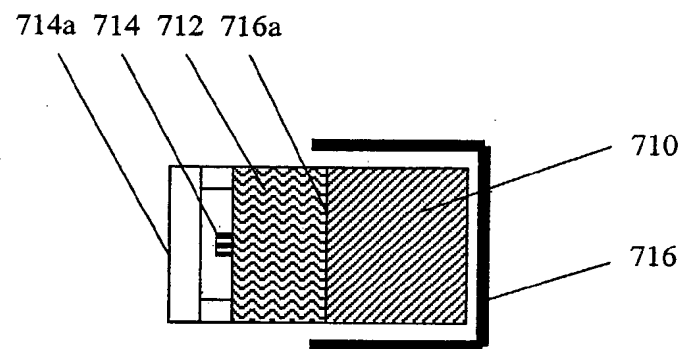
Figure 7

Figure 8A

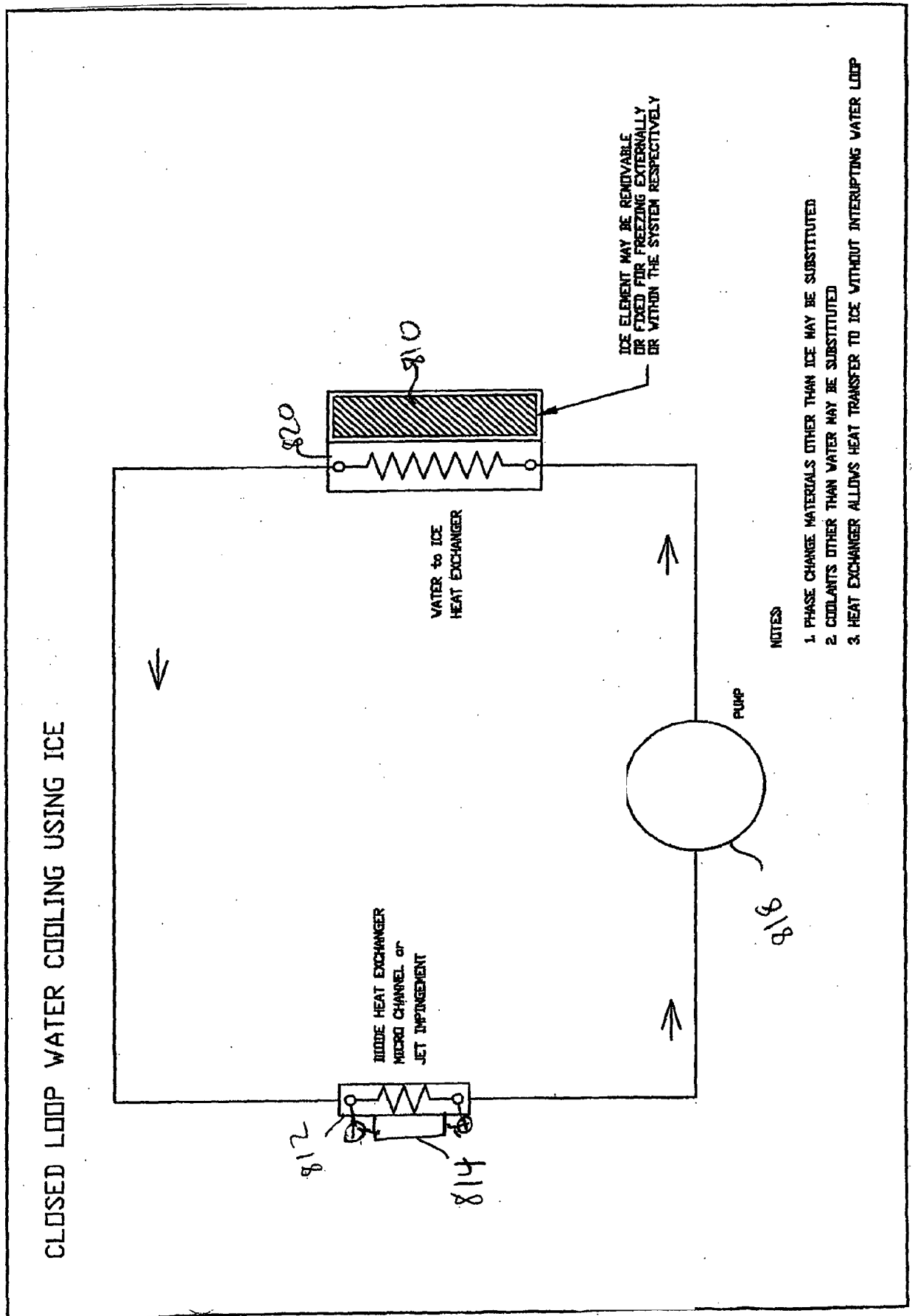
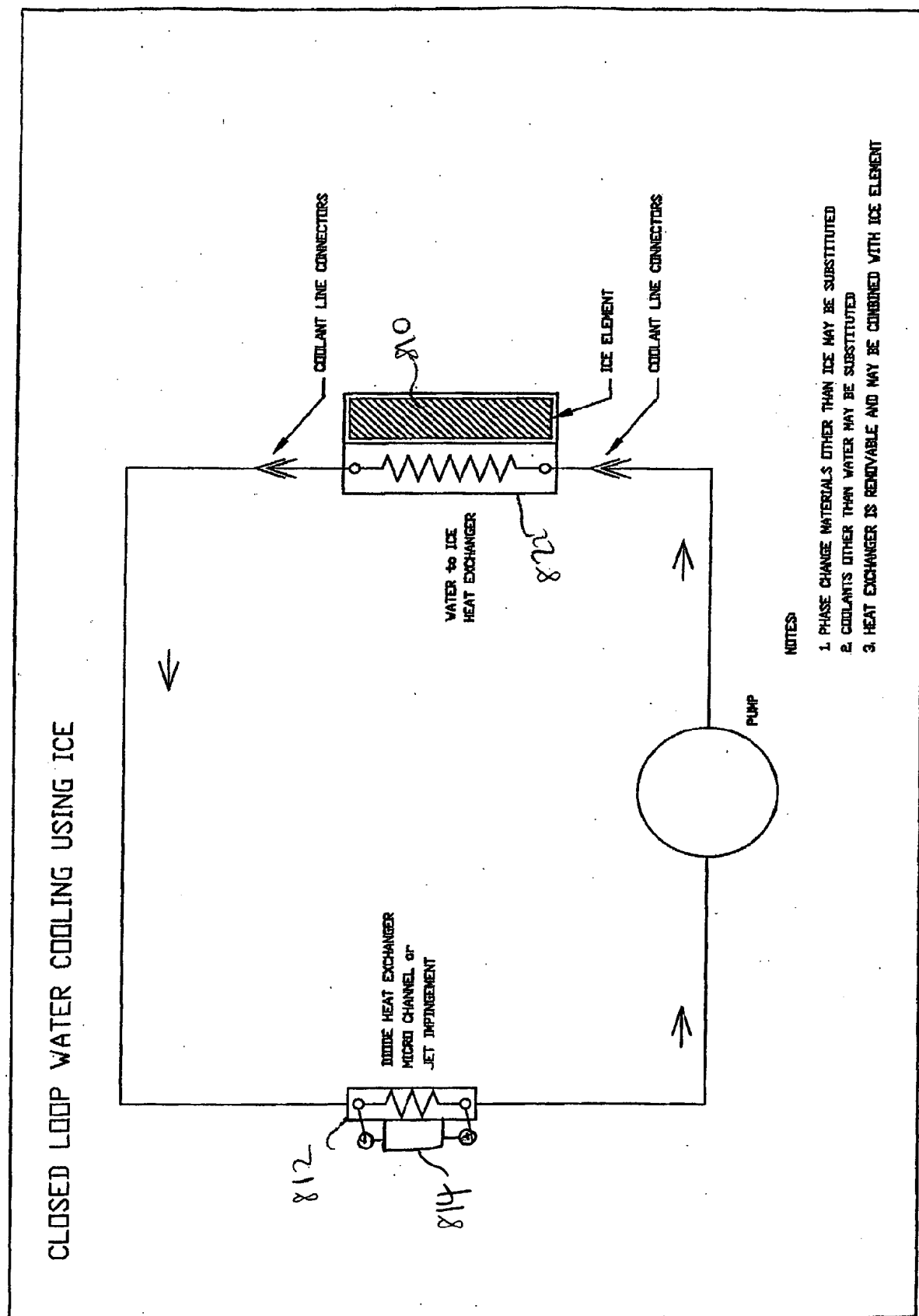


Figure 8B



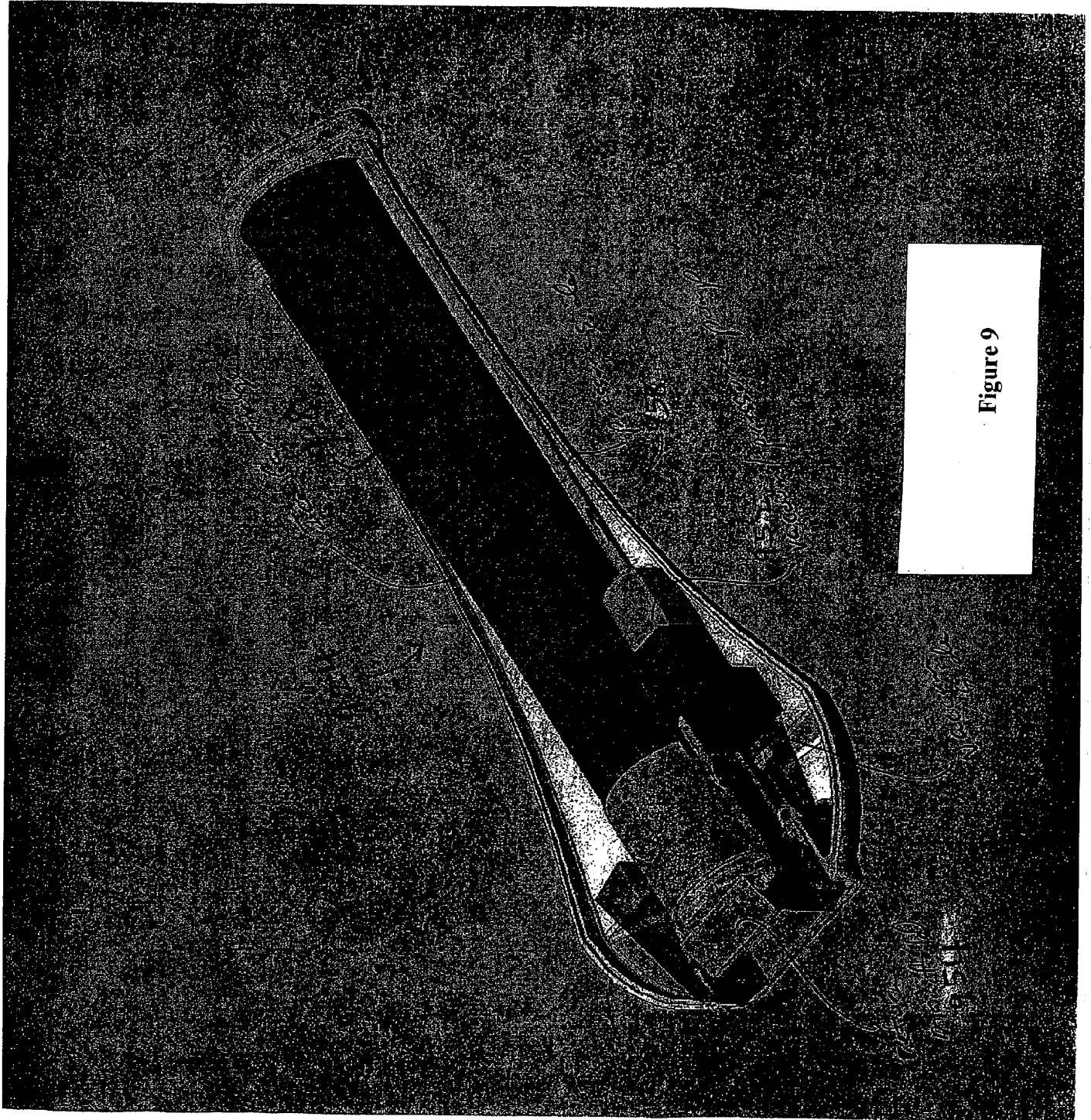


Figure 9

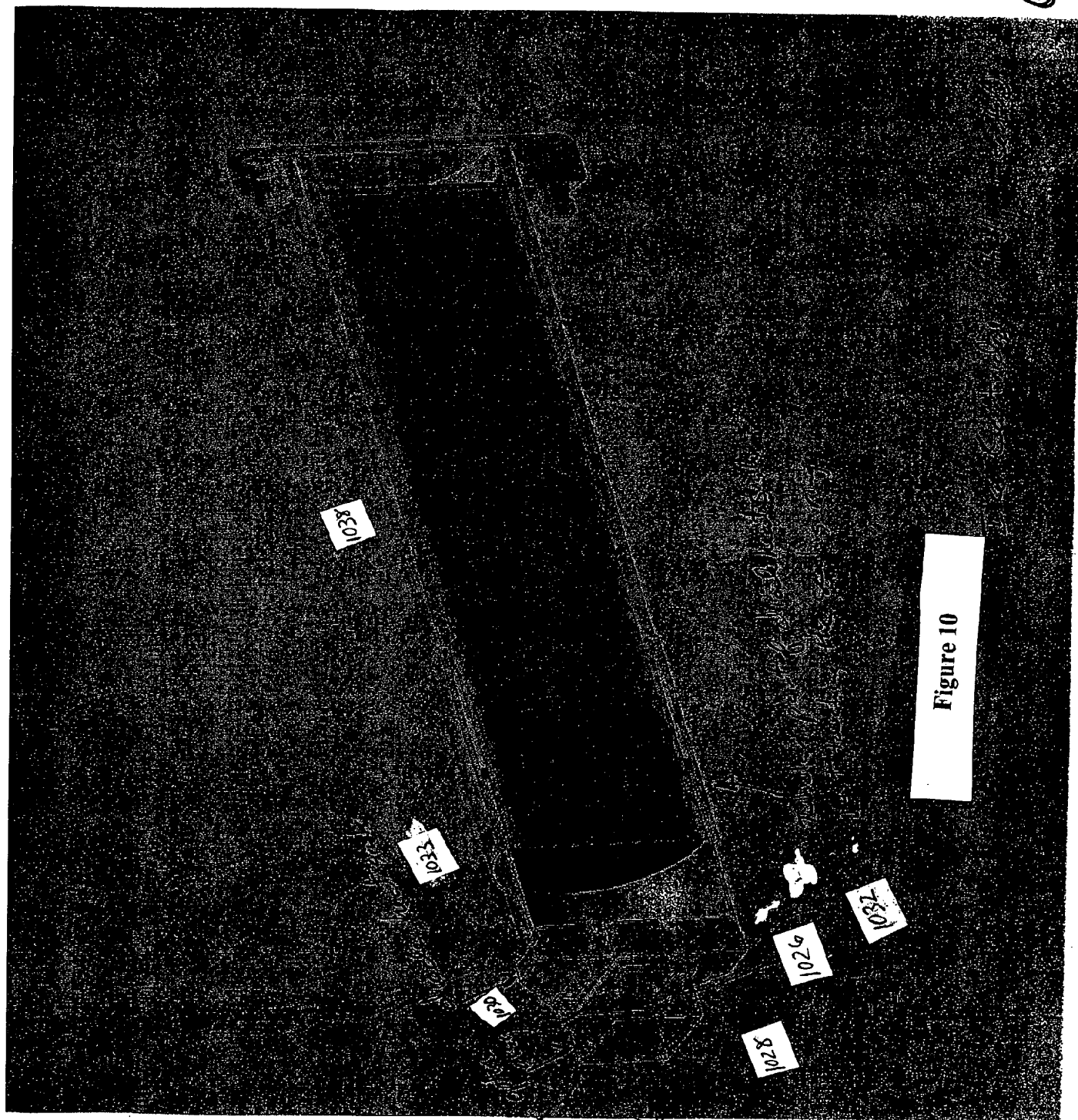


Figure 10

Yes

103

1028

1026

1032

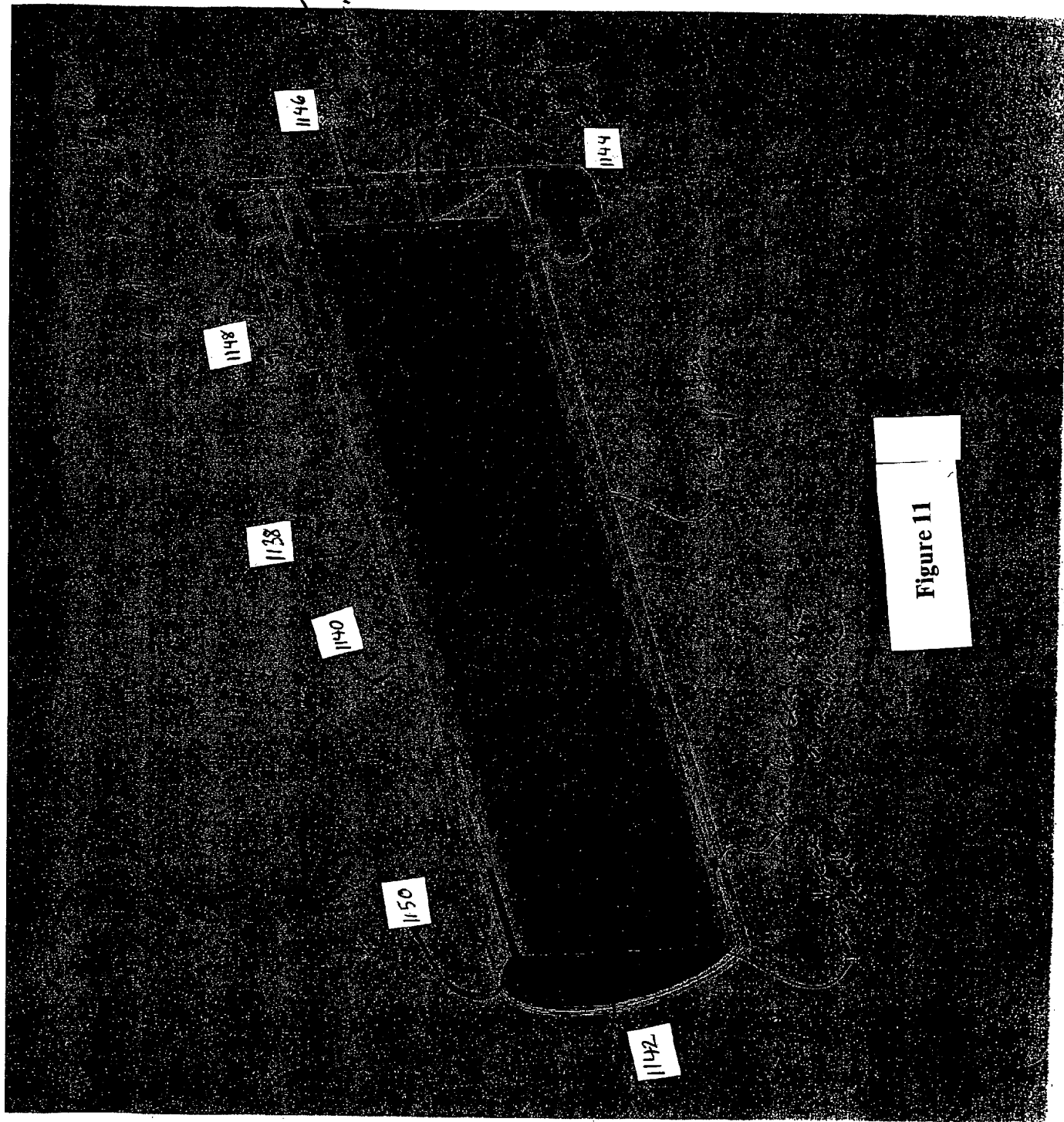
1033

1038

106

AA

pressure
in liquid



(c)

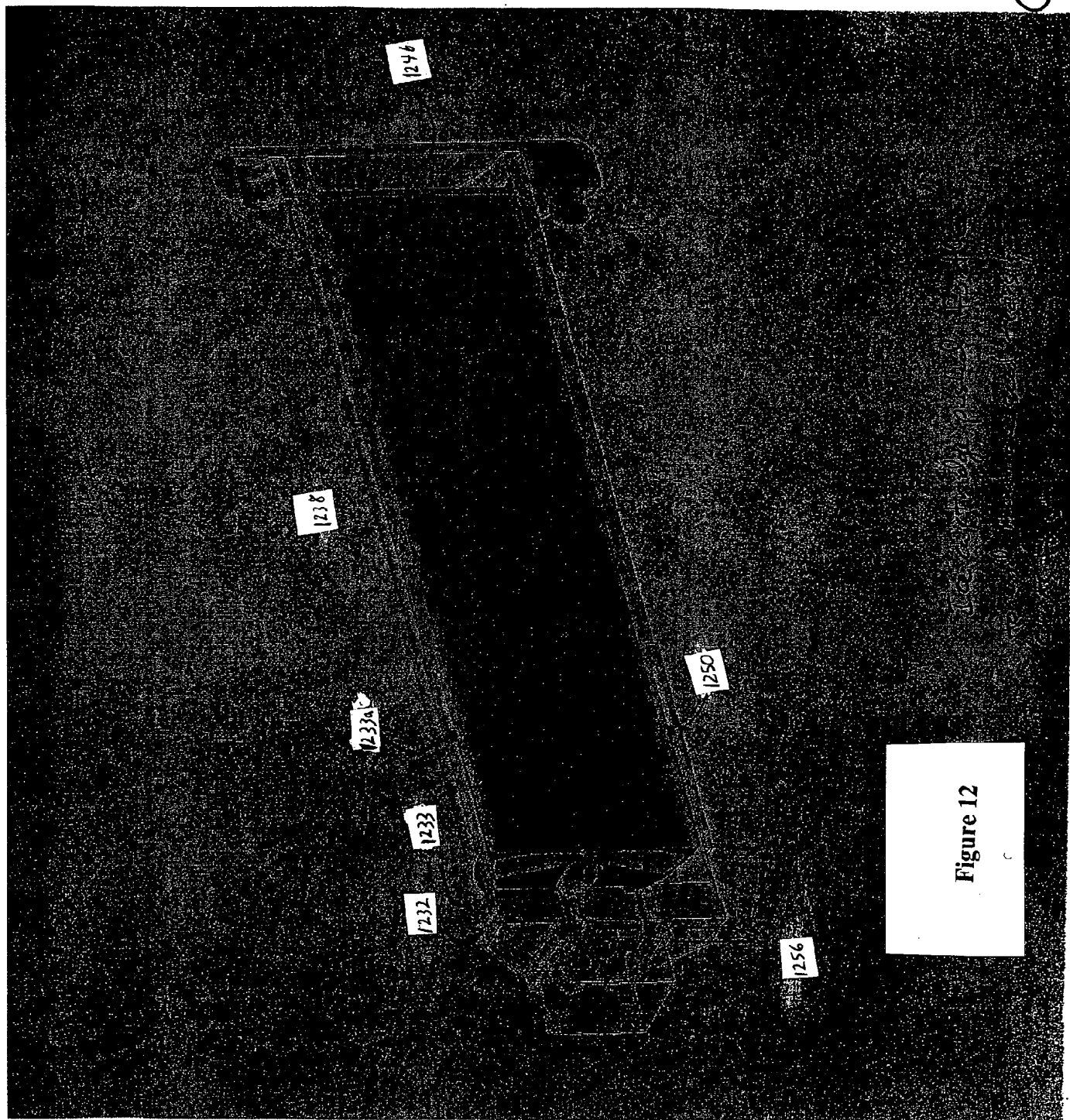
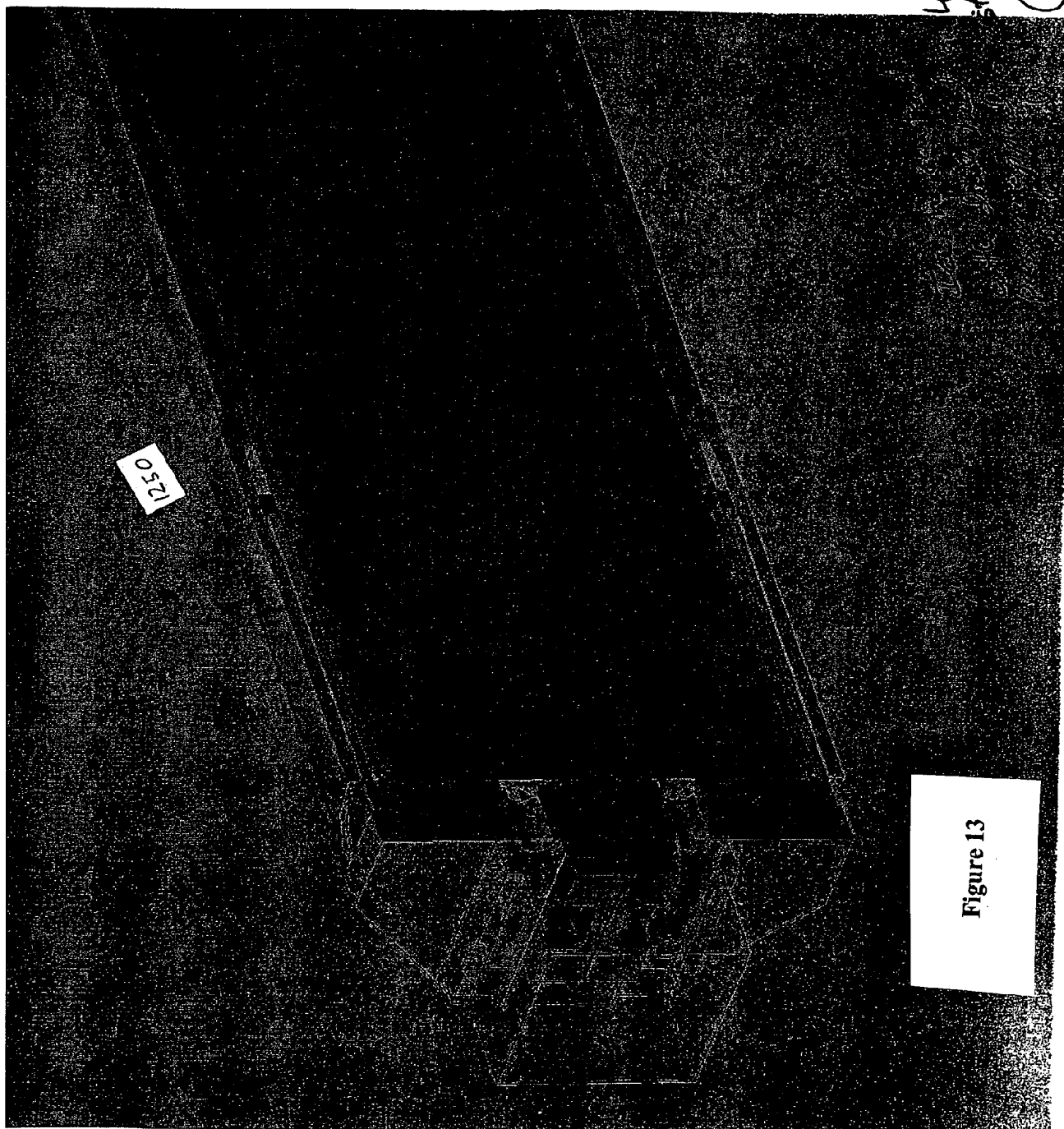
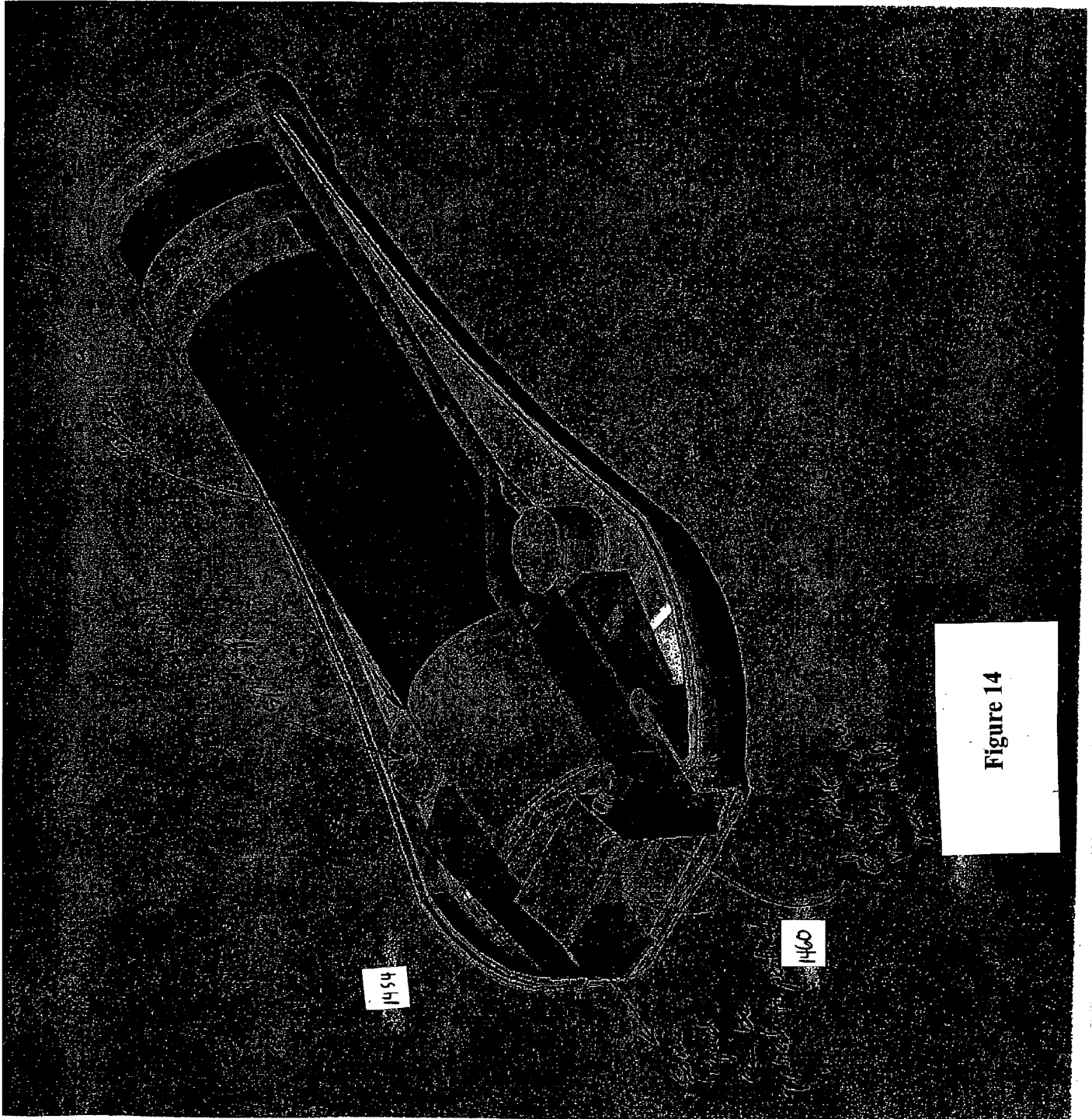
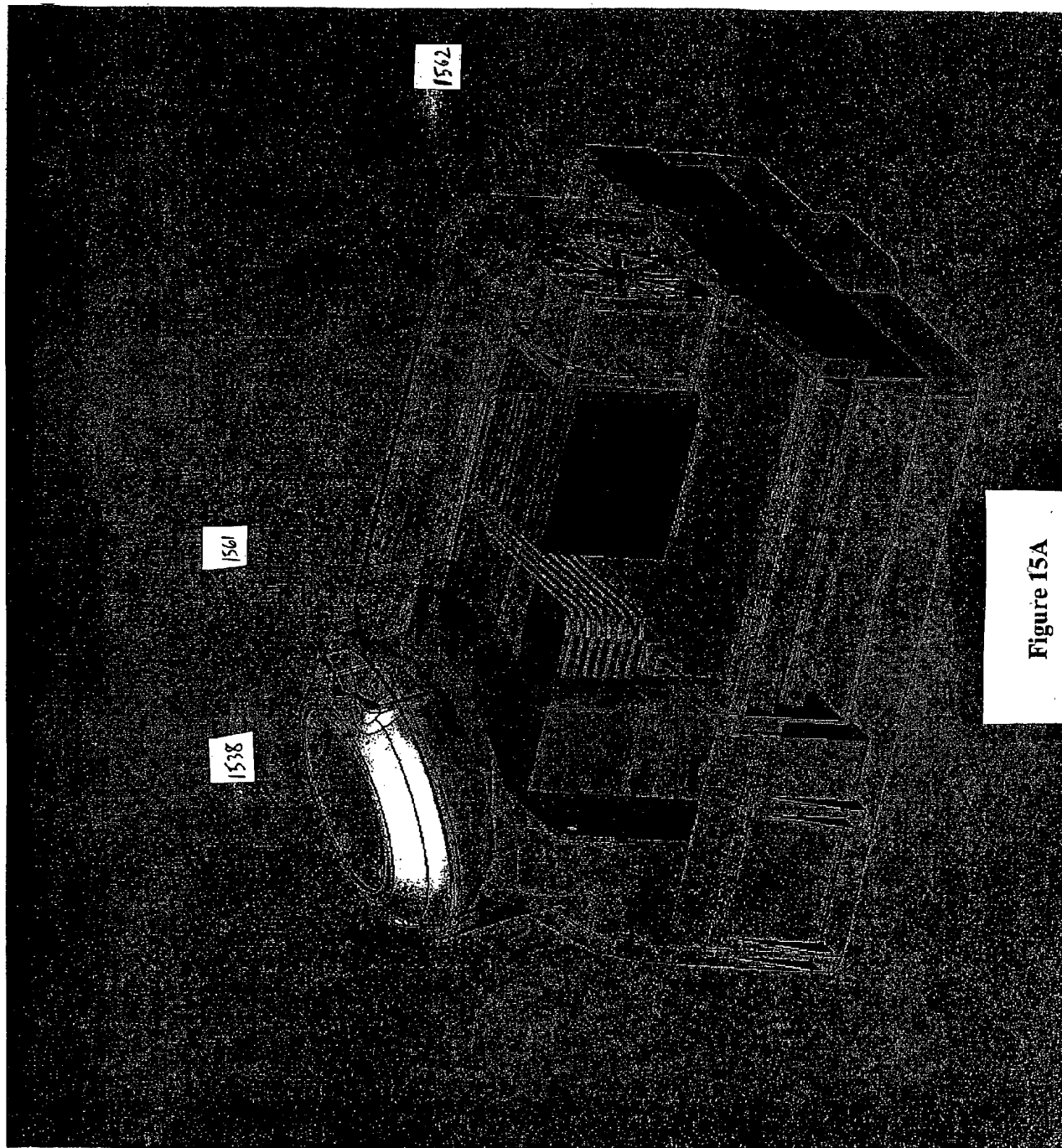
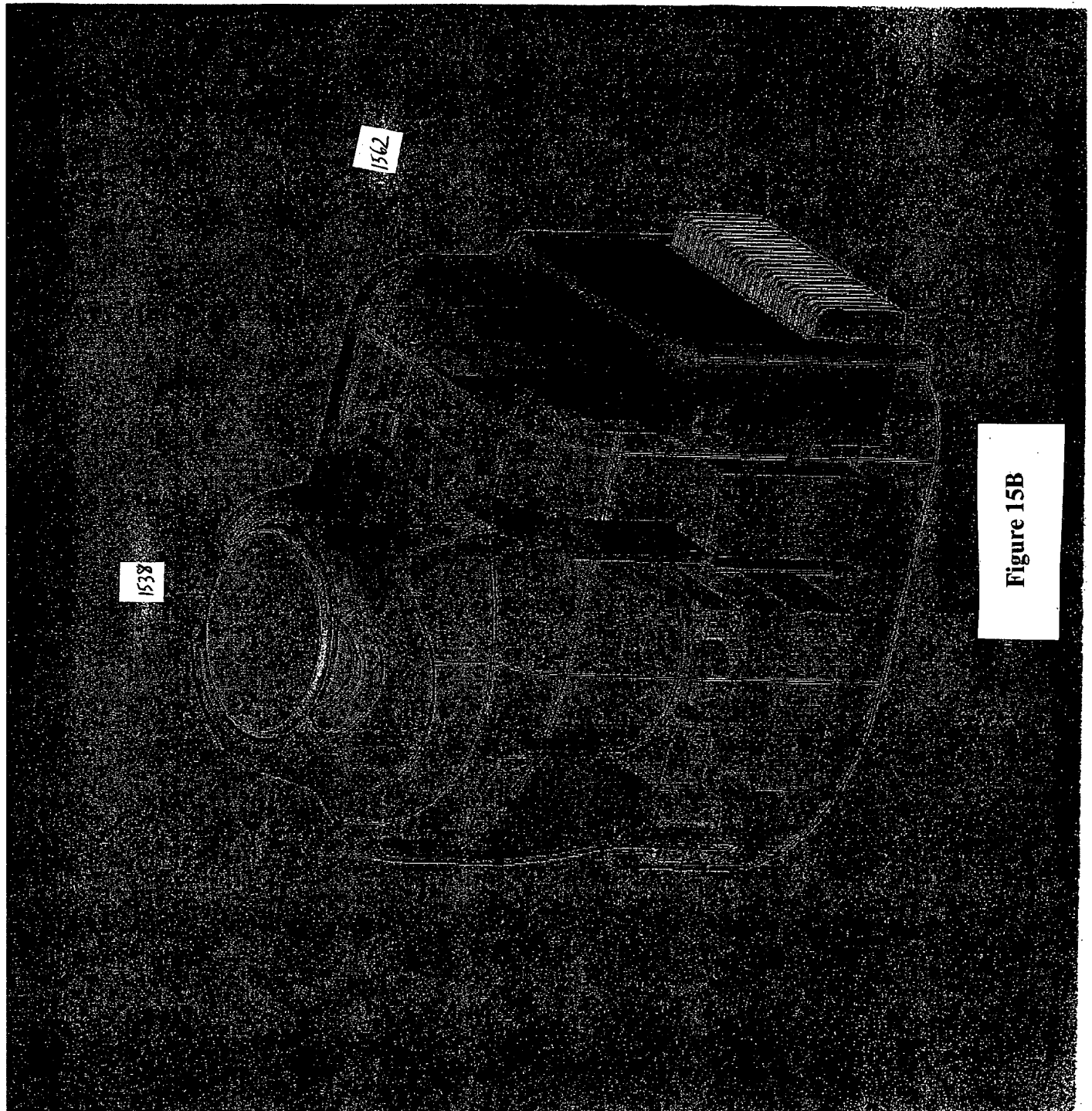


Figure 12









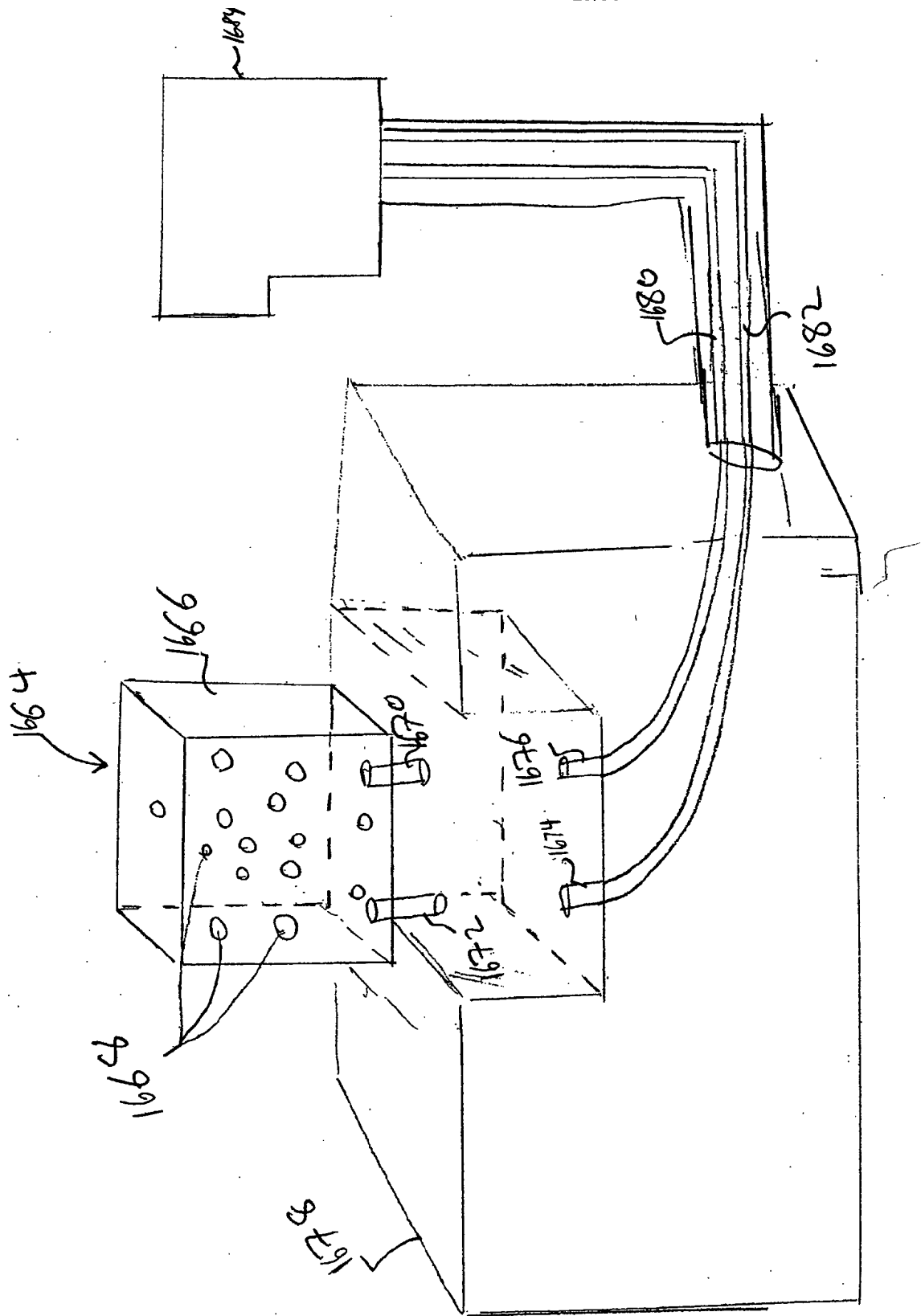


Figure 16

SL# enclosure

Ice Cassette
unit in base unit

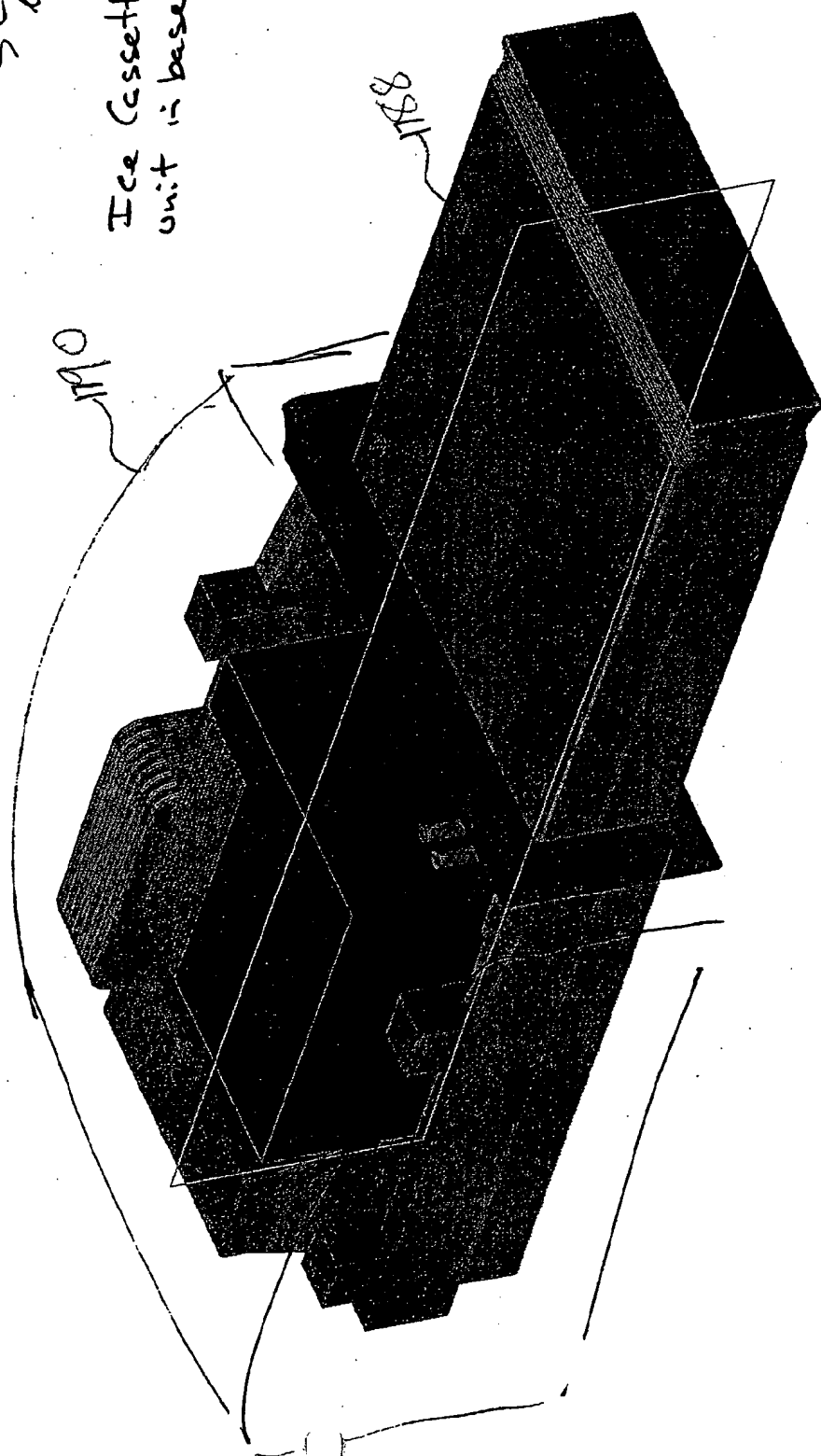
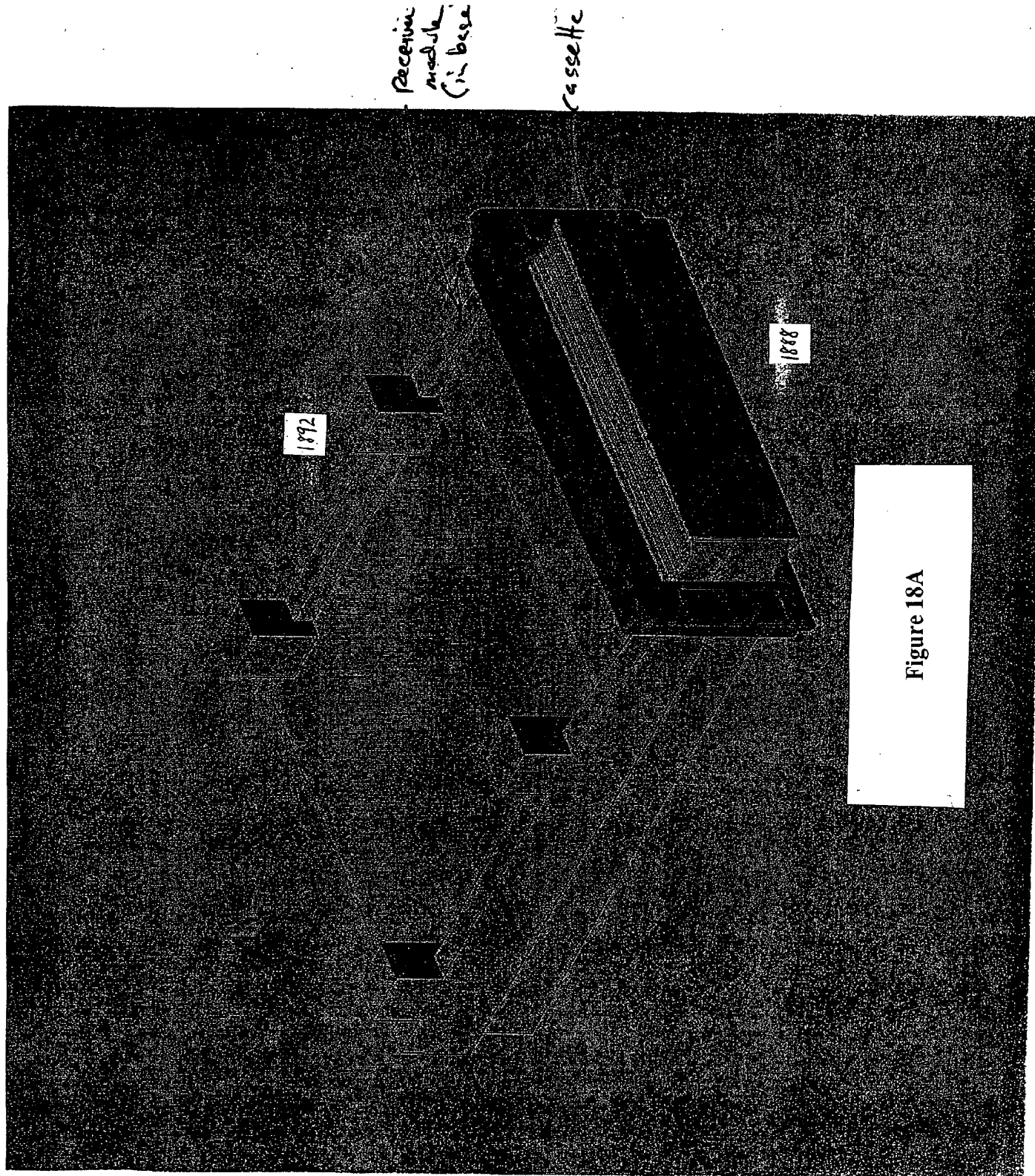
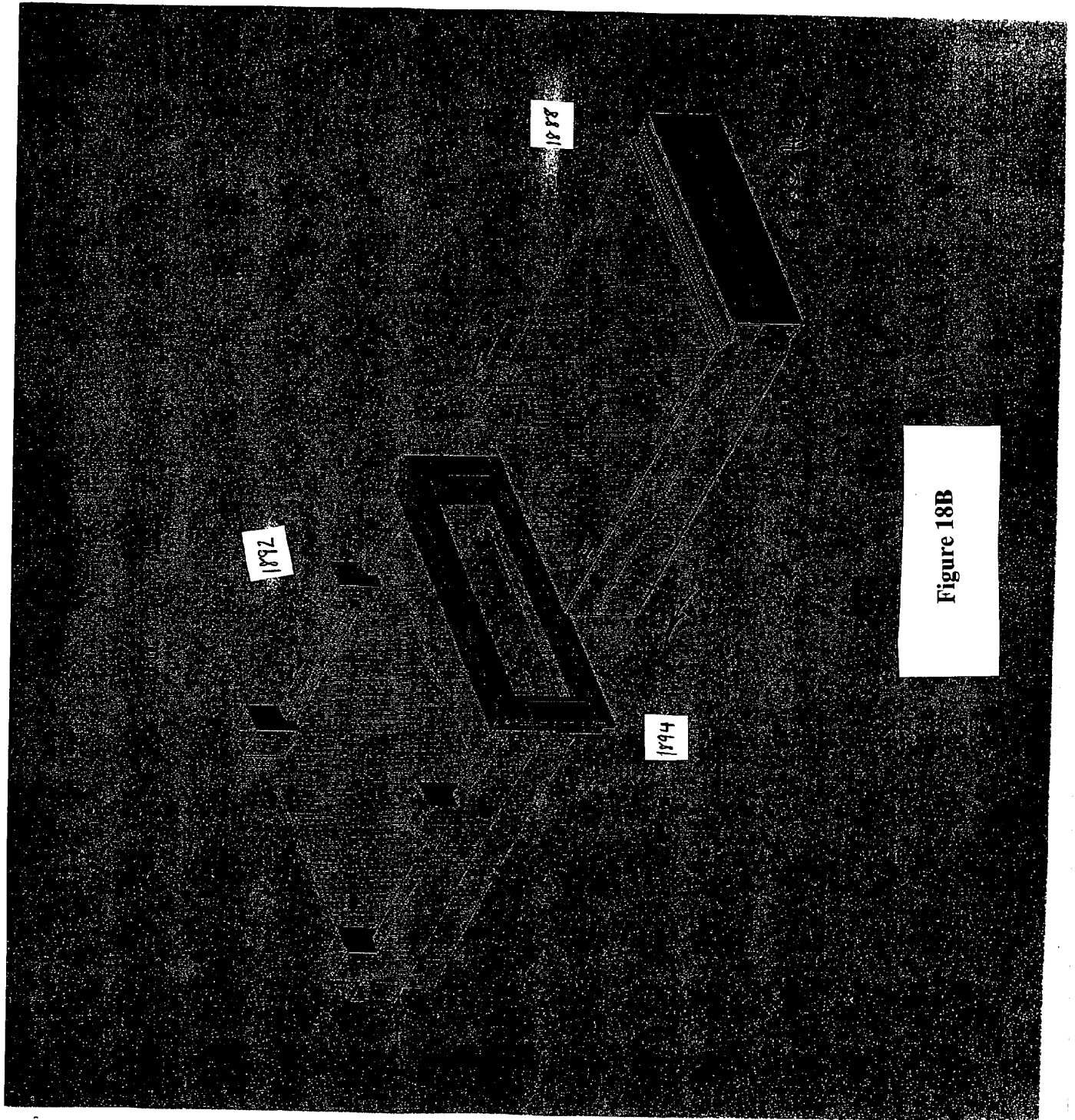
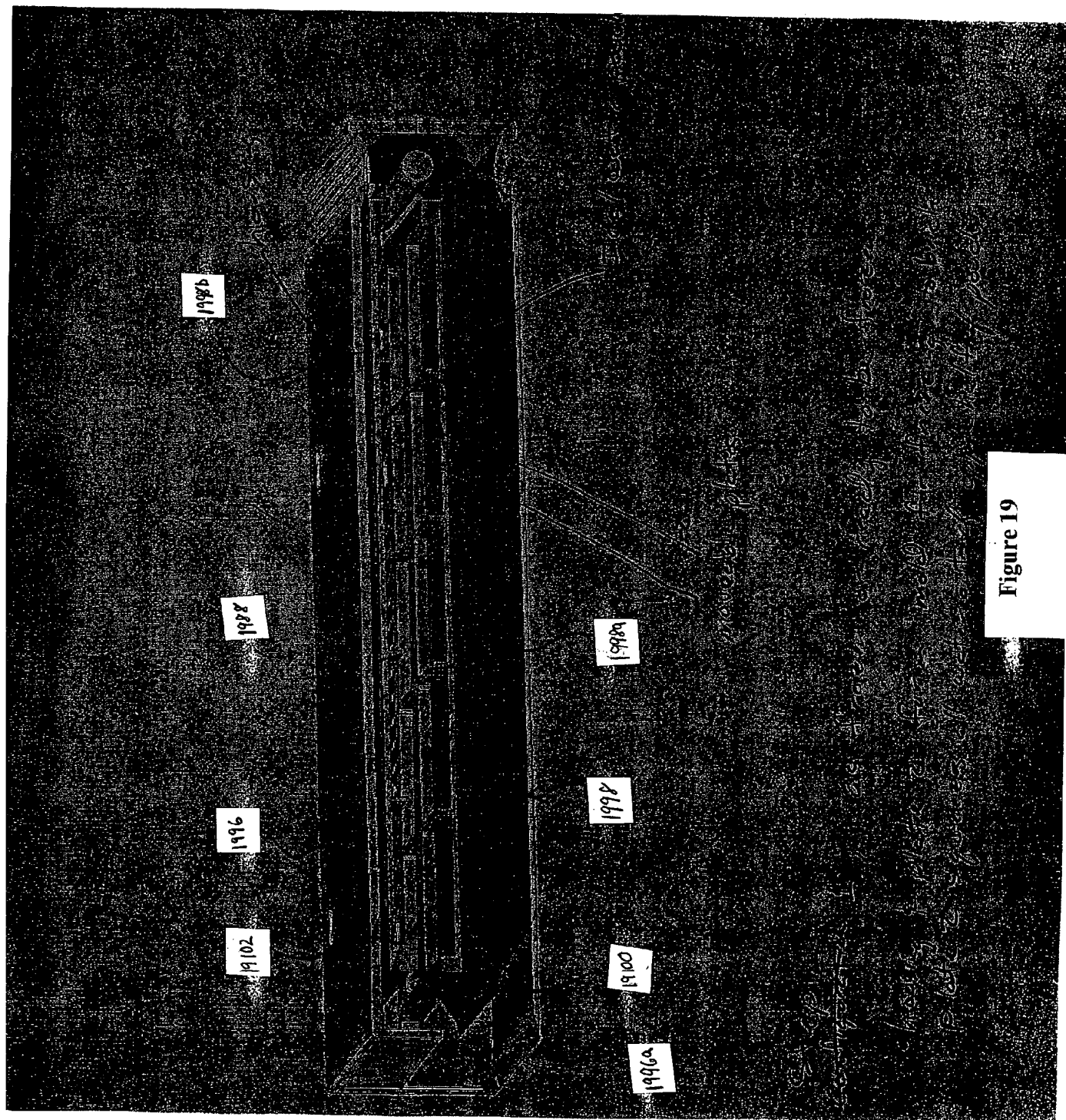


Figure 17







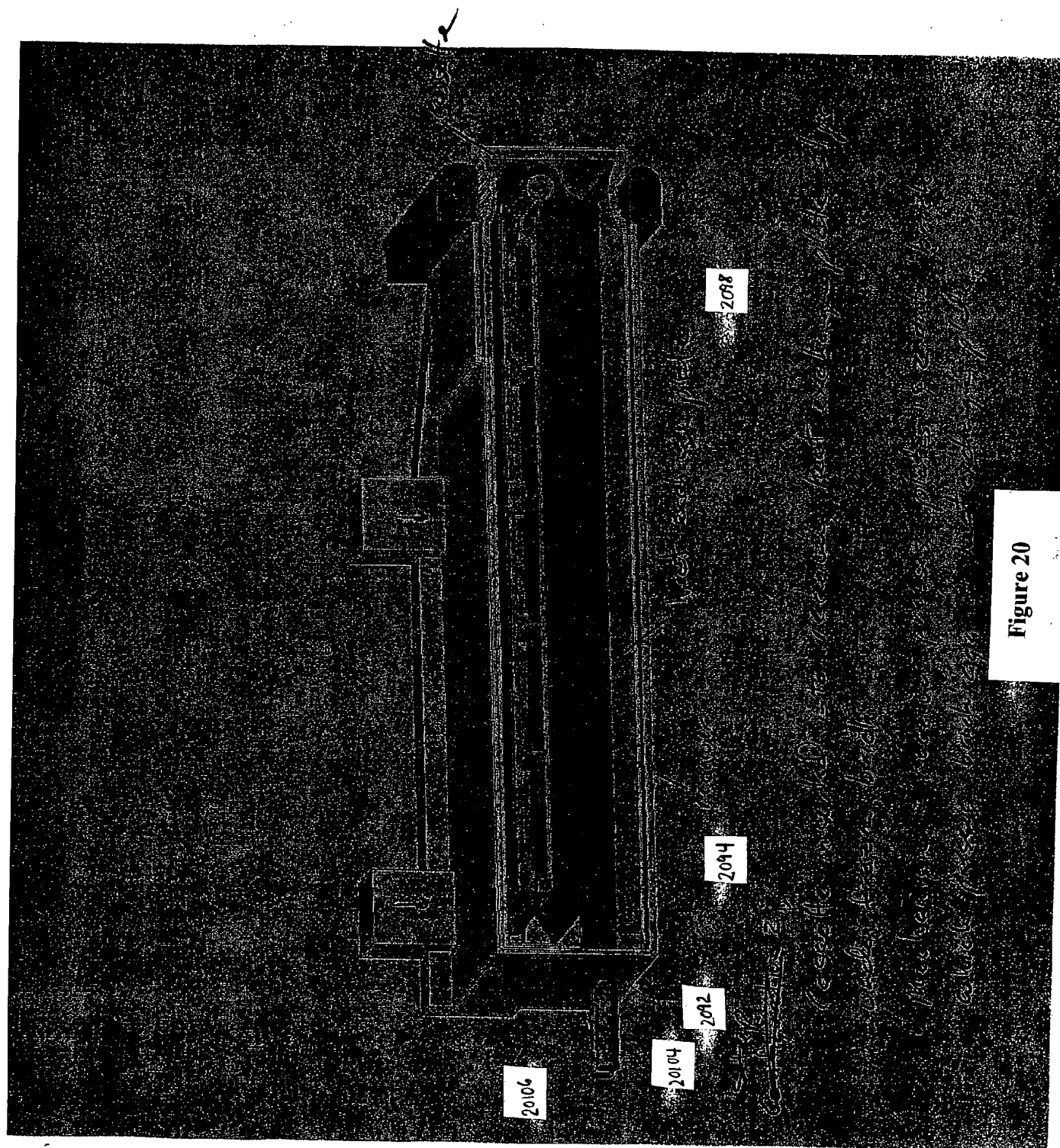
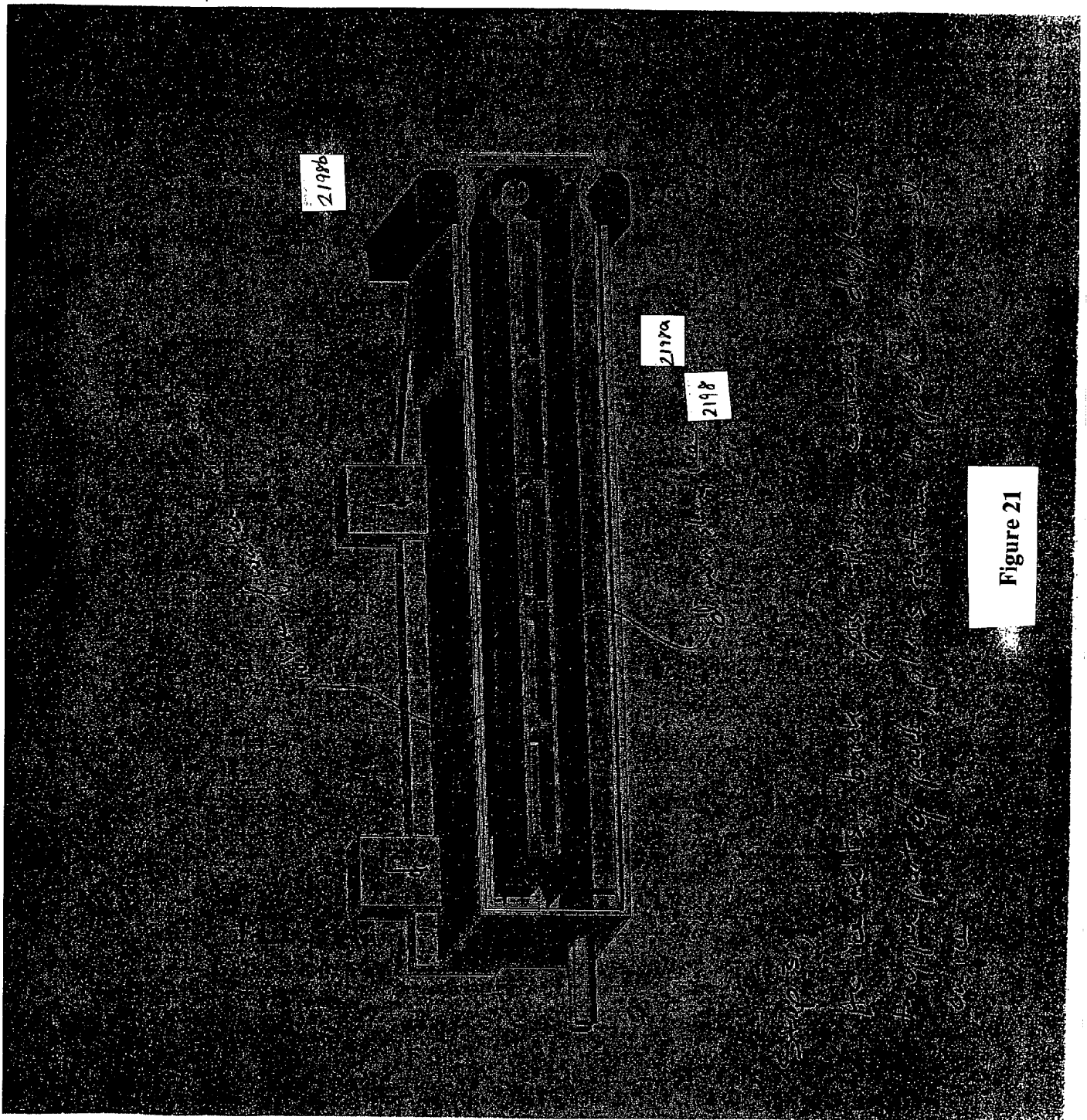


Figure 20



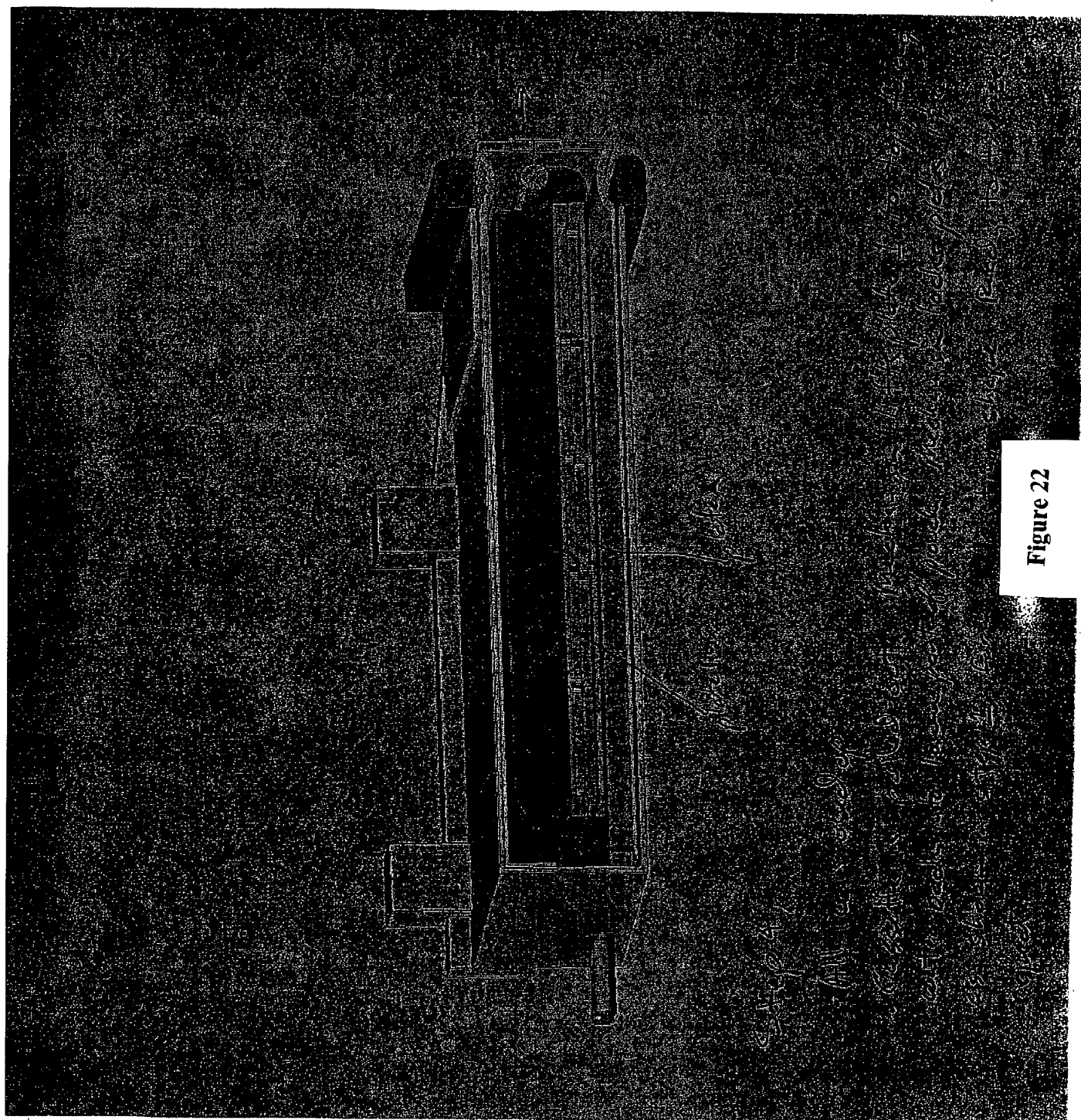
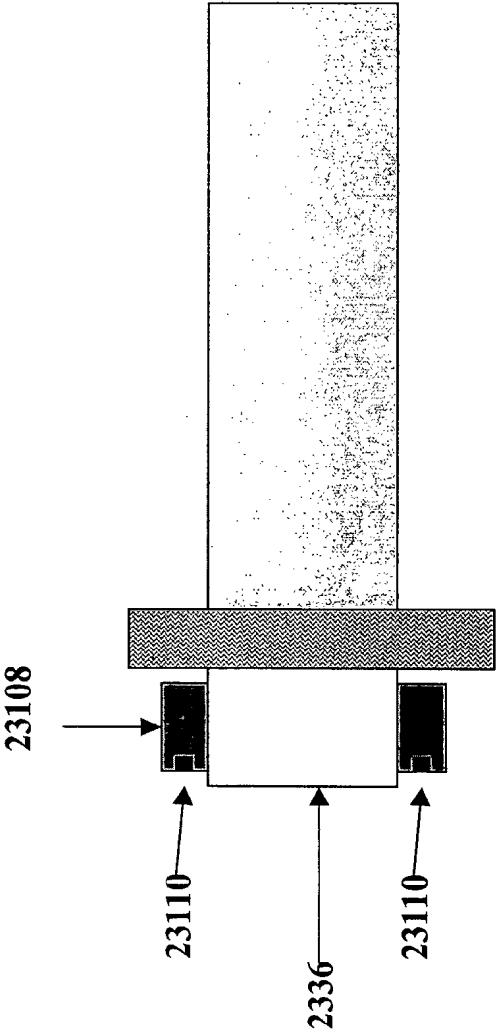


Figure 23



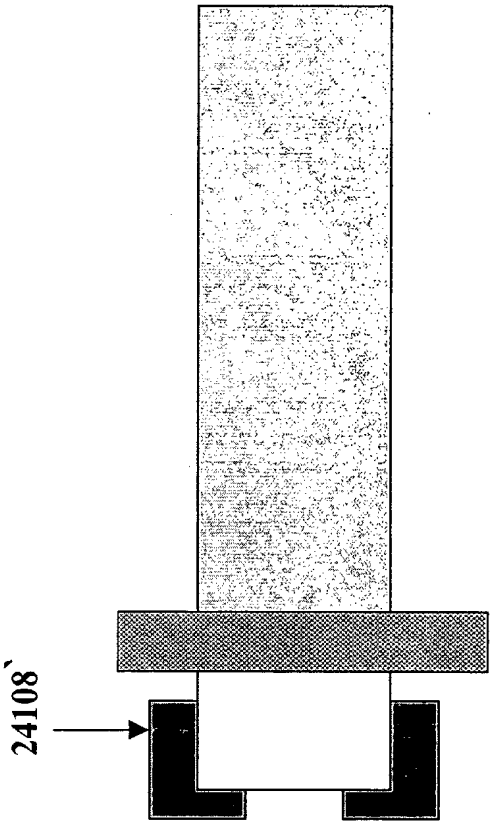


Figure 24A

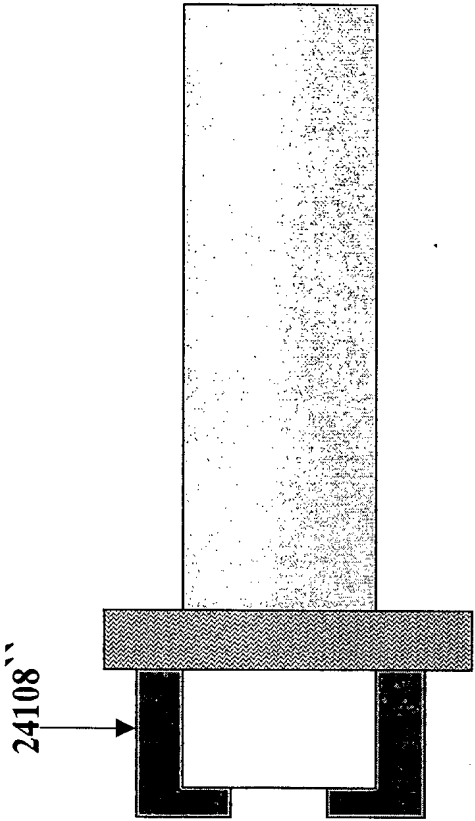


Figure 24B

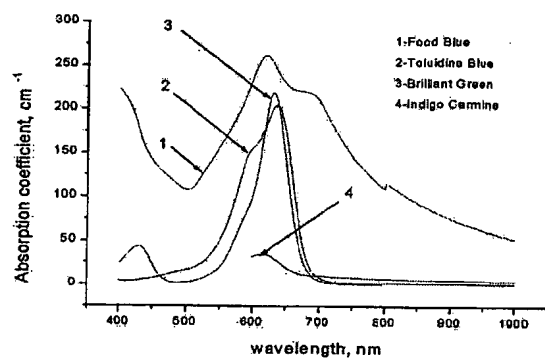


Figure 25A

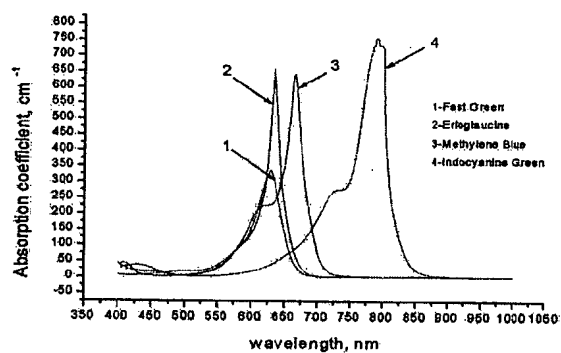


Figure 25B

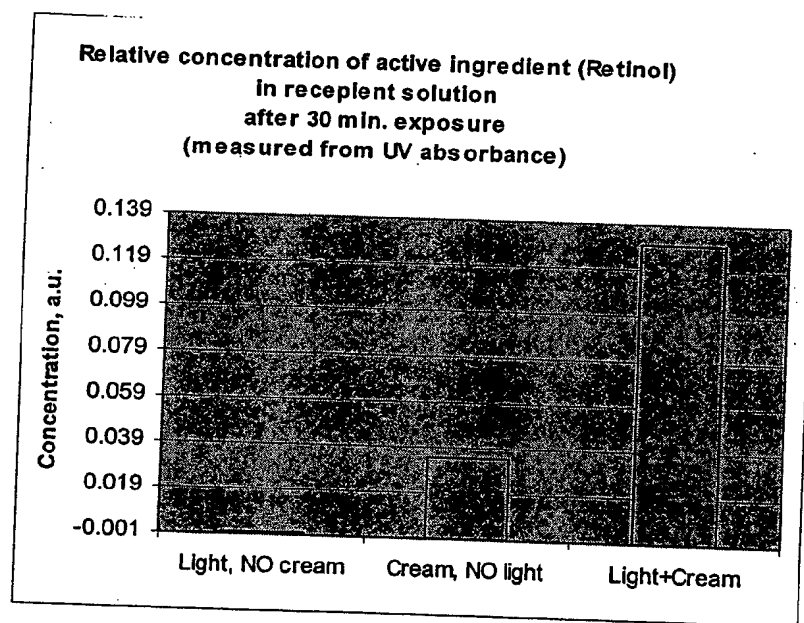


Figure 26

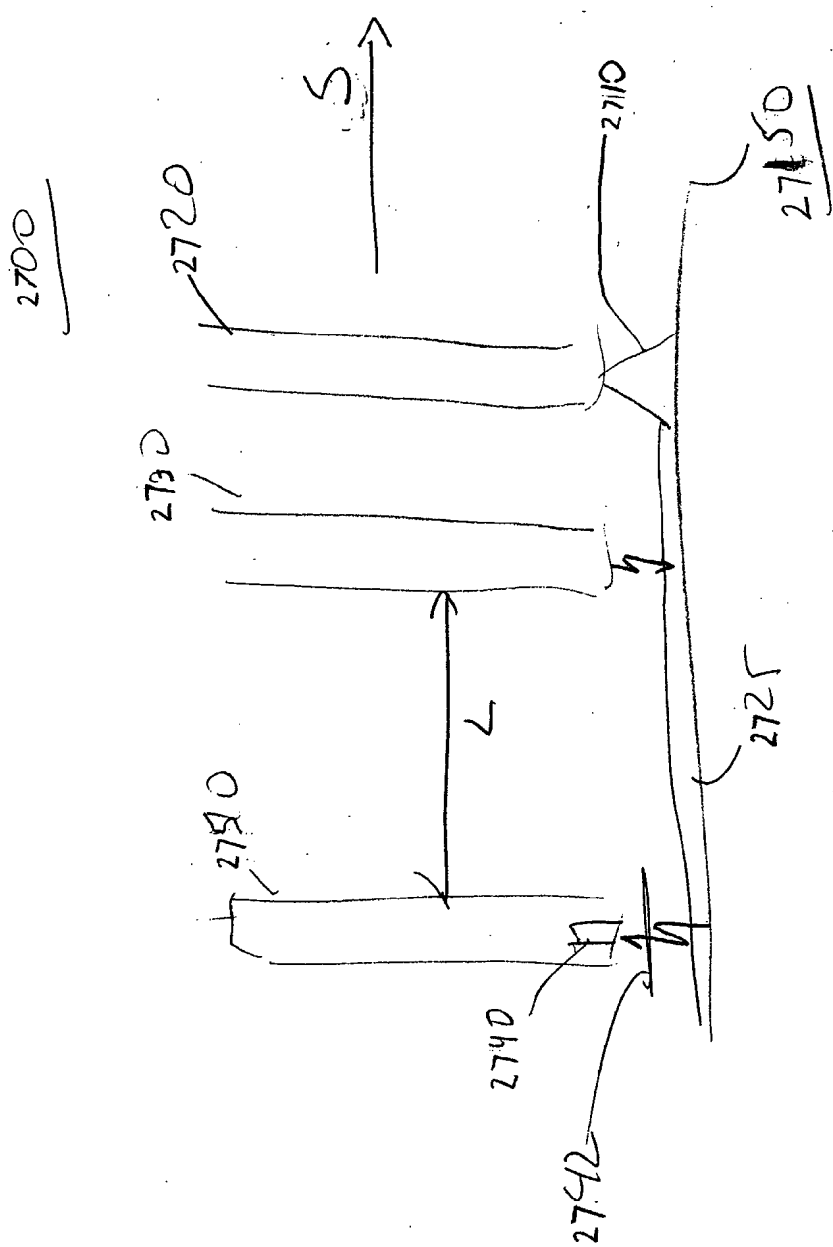


Figure 27

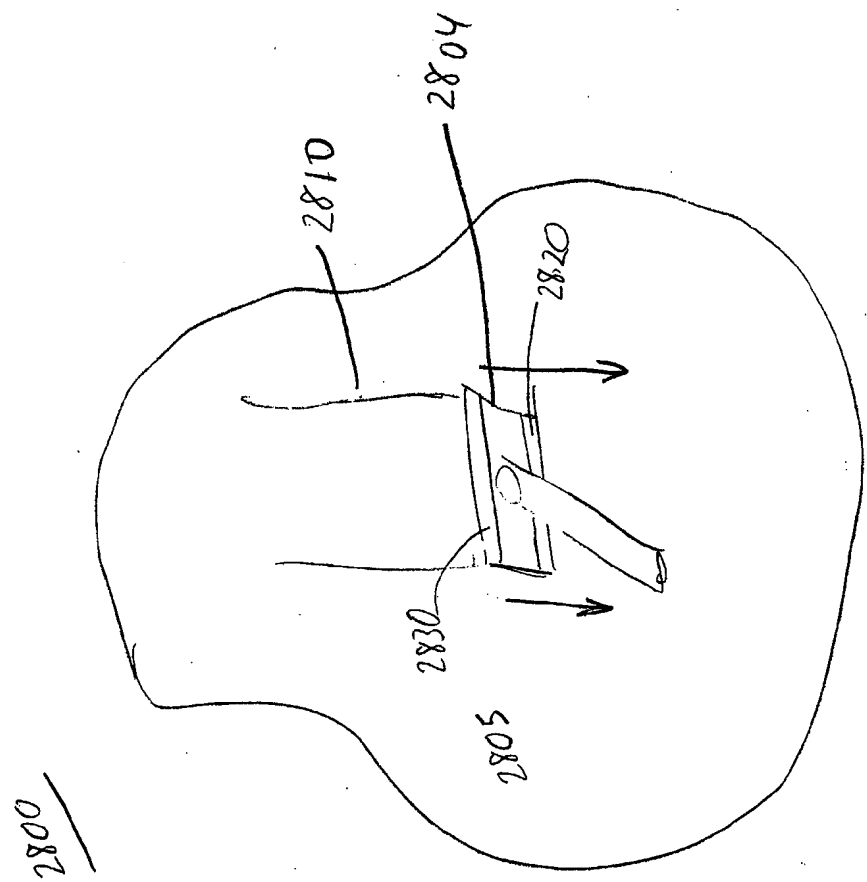


Figure 28

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| 60/458,861 | 27 March 2003 (27.03.2003) | US |
| 60/472,056 | 20 May 2003 (20.05.2003) | US |

V.; 1368 Bordeaux Street, Pleasanton, CA 94566 (US).
GROVE, Robert, E.; 28 Grey Eagle Court, Pleasanton, CA 94566 (US).

(74) Agent: **SEKIMURA, Gerald, T.**; Gray Cary Ware & Freidenrich LLP, 153 Townsend Street, Suite 800, San Francisco, CA 94107 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

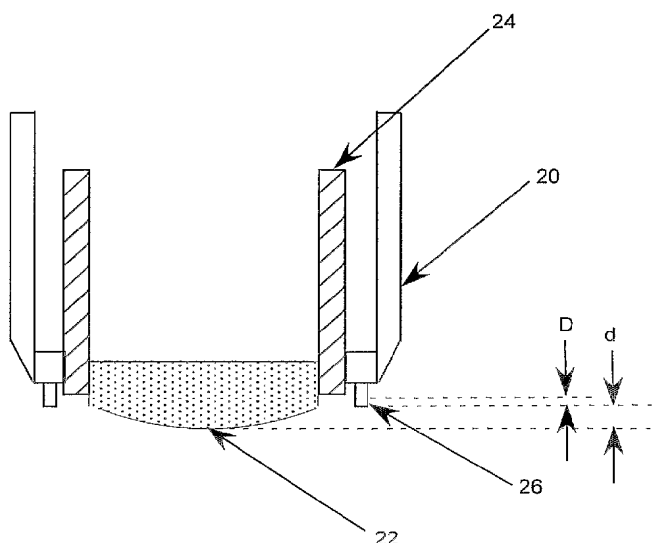
(71) Applicant (*for all designated States except US*): **SPECTRAGENICS, INC.** [US/US]; 7083 Commerce Circle, Suite I, Pleasanton, CA 94588 (US).

(72) Inventors: **ISLAND, Tobin, C.**; 955 Grosvenor Place, Oakland, CA 94610 (US). **WECKWERTH, Mark,**

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR,

[Continued on next page]

(54) Title: IN THE PATENT COOPERATION TREATY APPLICATION FOR PATENT



(57) Abstract: A skin contact sensor and method are disclosed in a dermatologic treatment device that includes a skin contacting structure, a treatment source capable of being activated to supply a dermatologic treatment through the skin contacting structure. A plurality of sensors are positioned around a periphery of the skin contacting structure, and control circuitry coupled to the plurality of sensors inhibits activation of the dermatologic treatment device unless contact with a compliant surface is sensed. Another embodiment employs a single sensor which is positioned distal to the skin contacting structure so that a non-compliant surface in contact with the skin contacting structure is unable to activate the single sensor.



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GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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IN THE PATENT COOPERATION TREATY
APPLICATION FOR PATENT

5 TITLE: METHOD AND DEVICE FOR SENSING SKIN CONTACT
INVENTORS: Tobin C. Island, Mark V. Weckwerth, and Robert E. Grove

PRIORITY

This application claims the benefit of priority under 35 U.S.C. §119(e) to
10 United States provisional patent applications nos. 60/452,591, filed March 6, 2003;
60/456,379, filed March 20, 2003; 60/458,861, filed March 27, 2003; 60/472,056,
filed May 20, 2003; and 60/456,586, filed March 21, 2003.

FIELD OF THE INVENTION

The present invention relates to devices and methods which involve skin
15 contact sensors for dermatologic treatment.

BACKGROUND OF THE INVENTION

Many skin treatment devices require contact between an active area of the
device and the skin for reasons of safety and/or efficacy.

For example, in light-based hair removal systems, the light energy is typically
20 delivered through a cooled transparent surface that makes contact with the skin. In
this case, the active area of the device is the cooled, light-emitting surface, and skin
contact to this active area is required for at least two reasons: (1) cooling - the cooled
surface protects the skin by conducting heat away from the epidermis, and (2) eye
safety - contact with the skin eliminates stray light which poses a significant eye
25 hazard. (Some light remits to the environment from outside the active area due to
scattering within the skin, but this light poses dramatically less risk than light directly
incident upon the eye or directly reflected off the skin surface).

Other examples of treatment devices that require skin contact include (1)
devices that require contact only to prevent light leakage, such as a UV illuminator

that requires no skin cooling but has a contacting baffle to prevent stray light, or (2) devices that require contact only for their mechanism of action and not to prevent light leakage, such as a thermal heater that delivers a pulse of heat through direct conduction to the skin. Other dermatological devices and methods that involve skin contact include ultrasound and radio frequency applications, such as wrinkle reduction. Some dermatological devices and methods provide skin contact through an interface material, such as ultrasound gel, oil, water, or index matching fluid. It is to be understood that these devices and methods are still considered to be skin contacting for the purposes of this application.

A significant problem for such devices is that the operator may angle or tilt the device's applicator such that it is not perpendicular to the skin. This can create the situation where the entire surface of the active area is not in contact with the skin, and therefore the objective of safety and/or efficacy of the skin contact will not be achieved. This situation is shown graphically in Figure 1 where an applicator 10 is pressed against a compliant surface 14 that represents skin. The face 11 of the applicator tip 12 represents the active area of the device. As shown in the figure, a non-perpendicular applicator can produce regions where no contact occurs, shown schematically as Region A. Clearly, light leakage could occur from such a region and conductive skin cooling or any other action dependent on contact would not occur or would be less effective.

Another problem for light-based devices is due to eyeglasses. Typical contact sensors would generally sense positive contact if an applicator was applied to a person's eyeglasses, creating a potential for emission directly into the eye that could lead to serious injury or blindness. A similar condition could be created with household window panes or other similar transparent surfaces, whereby a contact sensor could sense contact against the window and light could be dangerously emitted into the ambient environment. It would be desirable, therefore, for a dermatologic contact sensor not to be activated by eyeglasses or similar surfaces.

The mechanical compliance of the surface material (and/or applicator) is an important parameter in these problems. If the material is non-compliant, a non-perpendicular applicator would make contact only upon a line or a point and a large portion of the active area would not be in contact. If the material is very compliant, a non-perpendicular applicator could make contact across the entire active area. Skin has a mechanical compliance that varies due to differences in skin thickness,

elasticity, bone backing, and other parameters, but is generally moderately-compliant, such that reasonable levels of applicator angles can indeed produce substantial regions of non-contact for active areas typical of existing devices. This statement is supported by the patient burns that occur occasionally in the light-based hair removal industry; the burns have a shape that indicates a lack of contact cooling across the entire active surface attributed to a non-perpendicular applicator. Furthermore, the fact that skin is moderately-compliant is one parameter that distinguishes skin from eyeglasses, and this parameter could be exploited to make a contact sensor that is immune to eyeglasses or similar hard surfaces.

10

CURRENT STATE OF THE ART

Despite the importance of skin contact, existing commercial skin treatment devices do not typically directly sense skin contact. Instead, the systems generally rely on operator training and expertise, which increases the cost of treatments and lowers safety and efficacy (as demonstrated by the burns noted above).

15

There are, however, various means known in the art to sense skin contact for related devices, including resistive, capacitive, pressure, strain, mechanical, optical, imaging, magnetic, and temperature means.

20

U.S. patent 6,508,813 (granted Jan. 2003) to Altshuler describes the use of a temperature sensor near the skin-contacting end of a dermatology device. There may be various controls responsive to the temperature sensor. This patent is presumably the basis of the E-2000 commercial laser system manufactured by Palomar Medical Technologies.

25

Muller et al. (U.S. patent 5,360,426, granted Nov. 1994) describe a force-controlled contact applicator for laser radiation, including an element displaceably mounted so as to move in response to contact pressure. A spring may resiliently bias the element in opposition to the contact pressure to define a pre-given force within the displacement range of the element. There may be various controls responsive to the sensor.

30

U.S. patent 5,643,252 (granted Jul. 1997) to Waner et al. discloses a laser-based skin perforator that may incorporate a safety interlock. The safety interlock may be a spring-loaded mechanism that is depressed by skin contact to a location where a switch is closed and the laser will initiate a pulse of radiation.

Similarly, Muncheryan (U.S. patent 3,622,743, granted Nov. 1971) describes a laser-based typography eraser and microwelder that includes a spring-loaded retractable tip that activates the laser through a switch when the tip is depressed onto the working surface.

5 In U.S. patent application 2003/0032950 (published Feb. 2003) and PCT application WO 02/094116A1 (Published Nov. 2002), Altshuler et al. discuss a variety of skin contact sensors, including optical methods using the treatment beam or a separate light source, electrical contacts to measure resistance or capacitance, and mechanical sensors such as spring-loaded pins or buttons that may be located around
10 the perimeter of an optical element.

In U.S. patent application 2002/0005475 (published Jan. 2002), Zenzie describes a skin contact detecting method and apparatus based upon detecting light at a skin contacting surface. The invention may include a detector for sensing light at the surface and controls responsive to the detector.

15 A review of the state of the art shows that the existing devices and methods have important deficiencies. In particular, the existing designs do not solve the problem described above where the device applicator is applied at an angle and are not immune to contact by eyeglasses. For example, with the Altshuler temperature sensor, a fraction of the active area may be in contact with the skin and produce a
20 temperature profile indicative of contact, but the signal does not reasonably ensure that the *entire* active area is in contact. Similarly, spring-loaded mechanical mechanisms, such as described by Waner or Muller, could be activated by contact with eyeglasses and also do not reasonably ensure that the entire active area is in contact. Such designs may allow light leakage, regions of poor contact cooling, and
25 other safety and efficacy concerns associated with lack of skin contact. Furthermore, existing devices and methods are also unnecessarily complex, costly, unreliable, or have other impracticalities. For example, spring-loaded and sliding mechanisms are difficult to clean, are subject to variable friction loads, and add complexity to the assembly.

30 Thus, there is a clear need for a practical contact sensor for skin treatment devices that would ensure skin contact across the entire active area of the device and would not be activated by eyeglasses and similar hard surfaces. Such an invention would solve a problem of existing methods and devices that occurs when the device applicator is applied at an angle and improve eye safety. Furthermore, such an

invention may indeed be a requirement for the expected emerging market of consumer skin treatment devices, as these products cannot rely upon the trained and expert users of physician devices to achieve safety and/or efficacy.

SUMMARY OF THE INVENTION

5 The foregoing and other problems and disadvantages of contact sensors in skin treatment devices are overcome by the present invention of a dermatologic treatment device which includes a skin contacting structure, a treatment source capable of being activated to supply a dermatologic treatment through the skin contacting structure, a plurality of sensors around a periphery of the skin contacting structure, and control
10 circuitry coupled to the plurality of sensors and configured to inhibit activation of the dermatologic treatment device unless contact with a compliant surface is sensed.

 In one embodiment the treatment source includes a source of electromagnetic radiation, and the skin contacting structure comprises a window through which electromagnetic radiation is emitted. The source of electromagnetic radiation and the
15 dermatologic treatment can be configured to provide hair regrowth inhibition. In such an embodiment, activation of the source of magnetic radiation will be inhibited unless contact with a compliant surface, such as skin, is sensed by way of the sensors.

 Other embodiments of the dermatologic treatment device are contemplated in which the treatment source is a source of electromagnetic radiation which is
20 configured for such treatments as acne treatment, photorejuvenation, wrinkle reduction, depigmentation, or repigmentation, and the activation of the source of magnetic radiation is inhibited unless contact with a compliant surface, such as skin, is sensed by way of the sensors.

 In further embodiments of the present invention, the ability to sense the
25 presence of a compliant surface is further enhanced by shaping or positioning the skin contacting structure with respect to the sensors so that the sensor activation points are distal from the skin contacting structure by a selected amount. For example, the skin contacting structure can have a surface which is convex in shape so that a non-compliant surface, such as an eyeglass lens, cannot come into contact with the sensors
30 when the skin contacting structure is in contact with the non-compliant surface. An alternative embodiment employs a skin contacting surface which is flat but positions the sensors to be recessed or distal with respect to the skin contacting surface.

Another embodiment employs a single sensor which is positioned distal to the skin contacting structure so that a non-compliant surface in contact with the skin contacting structure is unable to activate the single sensor.

In accordance with the present invention, a method for providing a skin
5 contact sensor in a dermatologic treatment device having a skin contacting structure and a treatment source capable of being activated to supply a dermatologic treatment through the skin contacting structure, includes the steps of positioning a plurality of sensors around a periphery of the skin contacting structure, and inhibiting activation of the treatment source unless contact with a compliant surface is indicated by signals
10 from the plurality of sensors. The method can further include the step of configuring the skin contacting structure so that the plurality of sensors is distal from the skin contacting structure by a predetermined amount. The configuring step can include the step of shaping the skin contacting structure to have a convex skin contacting surface.

It is therefore an object of the present invention to provide a skin contact
15 sensor and method suitable for use in dermatologic treatment devices.

It is another object of the present invention to provide a skin contact sensor and method for dermatologic treatment devices in which the skin contact sensor inhibits activation of a treatment source in the device unless contact with a compliant surface is sensed.

20 It is a further object of the present invention to provide a dermatologic treatment device having a skin contact sensor including a plurality of sensors positioned around a periphery of a skin contacting structure and circuitry coupled to the plurality of sensors and configured to inhibit activation of a treatment source in the device in the presence of a non-compliant surface.

25 It is still another object of the present invention to provide a skin contact sensor and method for use in dermatologic treatment devices in which a plurality of sensors are positioned around a treatment window and the plurality of sensors are distal to a skin contacting surface of the window by a selected amount.

It is a still further object of the present invention to provide a skin contact
30 sensor configuration and method in a dermatologic treatment device in which a three or more sensors are positioned around a treatment window and a skin-contacting surface of the treatment window is shaped so that the three or more sensors are recessed with respect to the skin-contacting surface by a selected distance.

These and other objectives, advantages and features of the present invention will be more readily understood upon considering the following detailed description of certain preferred embodiments of the present invention, and the accompanying drawings.

5

INCORPORATION BY REFERENCE

What follows is a list of citations corresponding to references which are, in addition to those references cited above and below, and including that which is described as background and the invention summary, hereby incorporated by reference into the detailed description of the preferred embodiments below, as
10 disclosing alternative embodiments of elements or features of the preferred embodiments that may not otherwise be set forth in detail below. A single one or a combination of two or more of these references may be consulted to obtain a variation of the elements or features of preferred embodiments described in the detailed description below. Further patent, patent application and non-patent references are
15 cited in the written description and are also incorporated by reference into the preferred embodiment with the same effect as just described with respect to the following references:

United States patent nos. 5,360,426; 5,643,252; 3,622,743; 6,508,813;
United States published application nos. 2002/0005475; 2003/0032950;
20 United States provisional patent applications no. 60/451,091, filed February 28, 2003; 60/456,379, filed March 20, 2003; 60/458,861, filed March 27, 2003; 60/472,056, filed May 20, 2003; 60/450,243, filed February 25, 2003; 60/450,598, filed February 26, 2003; 60/452,304, filed March 4, 2003; 60/451,981, filed March 4, 2003; 60/452,591, filed March 6, 2003; and 60/456,586, filed March 21, 2003, all of
25 which are assigned to the assignee of the subject application (collectively, the "Cross-Referenced Provisional Applications");

United States non-provisional patent application nos. 10/_____, filed February ___, 2004, entitled "Self-Contained Eye-Safe Hair-Regrowth-Inhibition Apparatus And Method," naming as inventors Tobin C. Island, Robert E. Grove, and
30 Mark V. Weckwerth; 10/_____, filed February ___, 2004, entitled "Eye-Safe Dermatologic Treatment Apparatus And Method," naming as inventors: Robert E. Grove, Mark V. Weckwerth, Tobin C. Island; and 10/_____, filed February ___,

2004, entitled "Self-Contained, Diode-Laser-Based Dermatologic Treatment Apparatus And Method," naming as inventors: Mark V. Weckwerth, Tobin C. Island, Robert E. Grove, all of which are assigned to the assignee of the subject application (collectively "the Cross-Referenced Non-Provisional Applications");

5 Published PCT application no. WO 02/094116;

 Attention is drawn to the aforementioned Cross-Referenced Provisional Applications and Cross-Referenced Non-Provisional Applications by the same inventors of the subject application that disclose various aspects of dermatologic devices. It is clear that one of ordinary skill in the art will recognize that aspects and
10 features disclosed in those applications may be configured so as to be suitable for use with the contact sensor device and method described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

 Figure 1 is a schematic illustration of an applicator that is angled or tilted with respect to the skin.

15 Figures 2A and 2B are a schematic illustration of an applicator tip that includes multiple contact sensors arranged around the periphery in accordance with the present invention.

 Figure 3 is a schematic illustration of an applicator tip that includes a convex window and multiple contact sensors in accordance with the present invention.

20 Figure 4 is a schematic illustration of an applicator tip that includes a flat window and multiple contact sensors in accordance with the present invention.

 Figures 5A, 5B and 5C are a schematic illustration of a resilient membrane contact sensor and an assembly in an applicator tip in accordance with the present invention.

25 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

 Figures 2A and 2B show a first aspect of the invention related to multiple contact sensors arranged around a periphery of a therapeutic surface of a device. In the cross section view, Figure 2B, housing 20 contains a skin contacting, therapeutic surface 22 attached by a supporting structure 24 (that may serve to cool or heat
30 surface 22) and multiple contact sensors 26. Surface 22 may be a surface emitting light, ultrasound, thermal pulses, radio frequency pulses, or other therapeutic energy.

In this example, the contact sensors are shown as mechanical switches with spring-biased actuating pins that depress into the switch body upon contact with skin, but could be any number of sensor types, including electrical contacts to sense resistance or capacitance or temperature sensors. The plan view of Figure 2A shows eight
5 contact sensors 26 arranged radially around the perimeter of skin-contacting surface 22. The switches can be hard-wire connected in series, such that the device is not considered to be in contact with skin unless all eight switches are "closed", or could be arranged in series and parallel configurations, or could be sampled by an electronic circuit with a variety of hardware or software algorithms. In practice, the sensor type
10 and properties, the number of sensors, the geometry of the sensor placement, and the electronic circuitry for the sensors would be chosen so as to provide a positive indication of skin contact across the entire surface 22 as required by the use of the device in which the sensor is located.

Figure 3 shows a second aspect of the invention related to contact immunity to
15 eyeglasses and similar non-compliant surfaces. In this figure, housing 20 contains a skin-contacting, therapeutic surface 22 attached by a supporting structure 24 (that may serve to cool or heat surface 22) and multiple contact sensors 26, shown again in this example as mechanical switches with actuation pins. The tips of the actuation pins are recessed a distance "d" from the outermost location of surface 22. Distance "D"
20 represents the distance that the actuation pins travel before the switch changes state. With this geometry, contact with a hard, relatively flat surface such as eyeglasses or plate glass could not activate all of the contact sensors simultaneously. On the other hand, an appropriately compliant material under sufficient pressure could conform to the surface 22 and also depress all of the actuators at least a distance of "D", thereby
25 indicating positive contact with the compliant material. Such a design provides both a high degree of confidence that the entire active area of the device is in contact with the skin and inhibits undesired activation from contact with eyeglasses or similar surfaces.

In Figure 3, a skin-contacting surface 22 is shown as convex but, as shown in
30 Figure 4, the surface may be flat, or have other geometries. Figure 4 also shows an example where the sensors are electrical contacts and are located a distance "d" below the skin-contacting surface 22, in order to provide high confidence that the entire surface 22 is in contact with a compliant surface.

Thus, in accordance with the present invention the contact sensors 26 are positioned to have a sensor activation point which can be in the same plane as the skin- contacting surface 22 or, preferably, distal to skin-contacting surface 22, for example from about 0 mm to about 1 mm. More preferably, the sensor activation
5 point is about 0.1 mm to 1 mm distal to the skin-contacting surface. As illustrated in Figures 3 and 4, the above can be achieved by selecting the geometries of skin- contacting surface 22 and/or the positioning of the contact sensors 26.

Figures 5A, 5B and 5C show a preferred embodiment of the invention. In Figure 5A, a front view is shown of a dermatologic applicator tip comprising a flat
10 skin-contacting surface 50 surrounded by a bezel 60 and supported by a structure 90. Protruding from the bezel are three mechanical contact sensor “buttons” formed as part of a resilient membrane 70. A cross-section view is shown in Figure 5B (labeled “SECTION A-A”), and a detailed cross-section view of a portion of the applicator tip is shown in Figure 5C (labeled “DETAIL B”). Referring to Figure 5C, resilient
15 membrane 70 is shaped such as to have a protruding button 72 separated from the rest of the membrane by a thin web 74. Upon sufficient force to the top (or outermost surface) of the button 74, the web deforms such that the opposite surface 76 of the button comes into contact with printed circuit board (PCB) 80 which is supported by element 90. The surface of the button that contacts PCB 80 is coated with a
20 conductive ink. PCB 80 has exposed inter-digitated traces located under the button. Normally, the inter-digitated traces are not electrically connected to each other, but when a button is sufficiently depressed, its conductive surface electrically connects the traces, thereby forming a switch.

In a preferred embodiment, the state of each button switch is monitored
25 independently by a microprocessor which has a software algorithm that requires all three switches to be in the “closed” state for the device to be considered in contact. The algorithm preferably also requires that each button switch change state to the “open” state between treatment periods, such as between light-pulses, to assure that the buttons are not permanently in the “closed” state. Contact sensor failure could be
30 detected in this manner. Further details and information about circuitry for interfacing with and processing information from the above sensors, and for implementing control methodologies based on the switch states, suitable for use in the present invention can be found in the above mentioned Cross-Referenced Non-Provisional Applications and the Cross-Referenced Provisional Applications.

Also, in a preferred embodiment, the output for the skin treatment device may be automatically triggered by the contact sensor, improving ease of use and obviating the expense and complication of an additional triggering element, such as a finger trigger. For example, for a hair growth inhibition procedure, a therapeutic light pulse
5 could be automatically initiated upon positive contact. Note that the additional safety provided by ensuring contact across the entire active area of the device and immunity to activation from contact with eyeglasses is an important benefit to automatic firing.

In the preferred embodiment, membrane 70 is made of 40-60 durometer silicone, the button protrudes approximately 0.030 inches above the outermost portion
10 of the bezel 60, the diameter of the button is approximately 0.060 inches, the web thickness is approximately 0.005 inches, the web length is approximately 0.030 inches, and the gap between the traces on PCB 80 and the conductive surface of the button is approximately 0.005 inches. Membrane 70 is bonded to bezel 60 and PCB 80 except in the button regions. Furthermore, in this embodiment the top (or outmost
15 surface) of the button is recessed approximately 0.005 inches from the flat skin-contacting surface 50, which may emit light and may provide heat transfer between the skin and the device. This embodiment results in a very low activation force of less than 0.1 oz per button which can easily be provided by skin, yet has sufficient return force provided by the resilient material to be reliable. The three buttons are
20 sufficiently recessed as to reasonably ensure that the entire skin-contacting surface 50 is in contact while being immune to activation by eyeglasses and other similarly hard, flat surfaces, and yet are reliably triggered by moderately-compliant skin over a wide range of anatomical locations. The button size is large enough to be manufactured with standard techniques and provides sufficient skin contact area, yet is small enough
25 to make for a practical sized applicator tip 100. Furthermore, the embodiment is inexpensive, simple, largely waterproof and immune to dirt and other contaminants, and reliable.

The description above is to be considered one preferred embodiment of the invention. As is clear to one of ordinary skill in the art, numerous other embodiments
30 are possible, and may include at least the following alternative aspects.

Other types of sensors could be used, including sensors that work primarily with electrical means, mechanical means, or optical means, and are fundamentally digital or analog in nature (including strain gages, temperature sensors, capacitive sensors, resistive sensors, or acoustic sensors). Sensor types that provide additional

means to discriminate skin from other materials, such as resistive sensors or temperature sensors that could be limited to certain pre-established ranges typical for skin may be even more preferable, but can present other complications such as low signal levels or sensitivity to water films. Another configuration would include using
5 more than one type of contact sensor in a single device, such as combining thermal sensors with mechanical switches.

Various sensor geometries could be used, including varying the number of sensors, the effective size of the sensors, the actuation force or pressure required to produce a state change, the distance the sensor activation point is recessed from the
10 active skin-contacting surface of the device, and other such configurations. In a preferred embodiment of the present invention, the sensor active contact area – the area of the sensor which makes contact with skin or other surface – is less than 5 mm², and more preferably less than 2 mm². Also, preferably, the activation force for each sensor is less one (1) oz, and more preferably between about 0.001 oz to about
15 0.1 oz.

Likewise, other types of sensor circuitry could be used. The sensor output could be processed purely in hardware, or the device could employ various different software or hardware algorithms to improve safety, reliability, or effectiveness, such as allowing use if three of four buttons indicated contact. Additionally, the circuitry
20 could compare signals from the sensors for various additional purposes, such as to estimate the total heat flux through the contact surface.

While exemplary drawings and specific embodiments of the present invention have been described and illustrated, it is to be understood that that the scope of the present invention is not to be limited to the particular embodiments discussed. Thus,
25 the embodiments shall be regarded as illustrative rather than restrictive, and it should be understood that variations may be made in those embodiments by workers skilled in the arts without departing from the scope of the present invention, as set forth in the appended claims and structural and functional equivalents thereof.

In addition, in methods that may be performed according to preferred
30 embodiments herein and that may have been described above, the operations have been described in selected typographical sequences. However, the sequences have been selected and so ordered for typographical convenience and are not intended to imply any particular order for performing the operations, unless expressly set forth in the claims or as understood by those skilled in the art as being necessary.

CLAIMS

We claim:

1. A dermatologic treatment device comprising
a skin contacting structure;
5 a treatment source capable of being activated to supply a dermatologic treatment through the skin contacting structure;
a plurality of sensors around a periphery of the skin contacting structure; and
control circuitry coupled to the plurality of sensors and configured to
10 inhibit activation of the dermatologic treatment device unless contact with a compliant surface is sensed.
2. The dermatologic treatment device of claim 1, wherein the treatment source includes a source of electromagnetic radiation, and the skin contacting structure comprises a window through which electromagnetic radiation is emitted.
- 15 3. The dermatologic treatment device of claim 2, wherein the source of electromagnetic radiation and the dermatologic treatment are configured to provide hair regrowth inhibition.
4. The dermatologic treatment device of claim 2, wherein the source of electromagnetic radiation and the dermatologic treatment are configured to provide
20 acne treatment.
5. The dermatologic treatment device of claim 2, wherein the source of electromagnetic radiation and the dermatologic treatment are configured to provide photorejuvenation.
6. The dermatologic treatment device of claim 2, wherein the source of
25 electromagnetic radiation and the dermatologic treatment are configured to provide wrinkle reduction.
7. The dermatologic treatment device of claim 2, wherein the source of electromagnetic radiation and the dermatologic treatment are configured to provide repigmentation.

8. The dermatologic treatment device of claim 2, wherein the source of electromagnetic radiation and the dermatologic treatment are configured to provide depigmentation.

5 9. The dermatologic treatment device of claim 1, wherein the treatment source is configured to provide a wrinkle reduction treatment.

10. The dermatologic treatment device of claim 1, wherein the treatment source is configured to provide a depigmentation treatment.

10 11. The dermatologic treatment device of claim 1, wherein the control circuitry automatically activates the treatment source when contact with a compliant surface is sensed.

12. The dermatologic treatment device of claim 1, wherein the plurality of sensors sense changes in electrical parameters.

13. The dermatologic treatment device of claim 1, wherein the plurality of sensors sense changes in mechanical parameters.

15 14. The dermatologic treatment device of claim 13, wherein the plurality of sensors include a resilient membrane.

15. The dermatologic treatment device of claim 1, wherein the skin contacting structure has a skin contacting area, and the plurality of sensors are positioned to have a sensor activation point distal to the skin contacting area.

20 16. A dermatologic treatment device comprising
a window shaped to contact a surface and capable of heat transfer with the surface;
a source of electromagnetic radiation capable of being activated to supply a dermatologic treatment through the window;
25 one or more heat-transfer elements thermally coupled to the window;
three or more sensors around a periphery of the window; and
control circuitry coupled to the three or more sensors and configured to inhibit activation of the dermatologic treatment device unless contact with a compliant surface is sensed.

17. The dermatologic treatment device of claim 16, wherein the control circuitry automatically activates the source of electromagnetic radiation when contact with a compliant surface is sensed.

5 18. The dermatologic treatment device of claim 16, wherein the window has a convex outer surface.

19. The dermatologic treatment device of claim 18, wherein the three or more sensors are positioned to have a sensor activation point distal to the window.

20. The dermatologic treatment device of claim 19, wherein the three or more sensors sense changes in electrical parameters.

10 21. The dermatologic treatment device of claim 19, wherein the three or more sensors include mechanical switches.

22. The dermatologic treatment device of claim 19, wherein the three or more sensors include a resilient membrane.

15 23. The dermatologic treatment device of claim 19, wherein the control circuitry automatically activates the source of electromagnetic radiation when contact with a compliant surface is sensed.

24. The dermatologic treatment device of claim 16, wherein the window has a flat outer surface.

20 25. The dermatologic treatment device of claim 24, wherein the three or more sensors are positioned to have a sensor activation point distal to the window.

26. The dermatologic treatment device of claim 25, wherein the three or more sensors sense changes in electrical parameters.

27. The dermatologic treatment device of claim 25, wherein the three or more sensors sense changes in mechanical parameters.

25 28. The dermatologic treatment device of claim 25, wherein the three or more sensors include a resilient membrane.

29. The dermatologic treatment device of claim 24, wherein the control circuitry automatically activates the source of electromagnetic radiation when contact with a compliant surface is sensed.

30. A dermatologic treatment device comprising
5 a window shaped to contact a surface;
 a source of electromagnetic radiation capable of being activated to supply a dermatologic treatment through the window;
 three or more sensors around a periphery of the window and positioned to have a sensor activation point distal to the window; and
10 control circuitry coupled to the three or more sensors and configured to inhibit activation of the dermatologic treatment device unless contact with a compliant surface is sensed.

31. The dermatologic treatment device of claim 30, wherein the three or more sensors sense changes in electrical parameters.

15 32. The dermatologic treatment device of claim 30, wherein the three or more sensors sense changes in mechanical parameters.

33. The dermatologic treatment device of claim 32, wherein the three or more sensors include a resilient membrane.

20 34. The dermatologic treatment device of claim 30, wherein the three or more sensors each have an active contact area less than 5 mm².

35. The dermatologic treatment device of claim 34, wherein the active contact area is less than 2 mm².

36. The dermatologic treatment device of claim 30, wherein the sensor activation point is between zero to 1 mm distal to the window.

25 37. The dermatologic treatment device of claim 30, wherein the sensor activation point is between 0.1 mm to 1 mm distal to the window.

38. The dermatologic treatment device of claim 30, wherein each of the three or more sensors becomes active at a contact force of between about 0 oz. to about 1 oz.

39. The dermatologic treatment device of claim 30, wherein each of the three or more sensors becomes active at a contact force of between about 0.001 oz to about 0.1 oz.

40. The dermatologic treatment device of claim 30, wherein the window has a convex outer surface.

41. The dermatologic treatment device of claim 30, wherein the window has a flat outer surface.

42. The dermatologic treatment device of claim 30, wherein the control circuitry automatically activates the source of electromagnetic radiation when contact with a compliant surface is sensed.

43. A dermatologic treatment device comprising
a window shaped to contact a surface and capable of heat transfer with the surface;
a source of electromagnetic radiation capable of being activated to supply a dermatologic treatment through the window;
one or more heat-transfer elements thermally coupled to the window;
three or more mechanical sensors around a periphery of the window and positioned to have a sensor activation point distal to the window; and
control circuitry coupled to the three or more sensors and configured to inhibit activation of the dermatologic treatment device unless contact with a compliant surface is sensed.

44. The dermatologic treatment device of claim 43, wherein the three or more sensors include a resilient membrane.

45. The dermatologic treatment device of claim 44, wherein the three or more sensors each have an active contact area less than 5 mm².

46. The dermatologic treatment device of claim 45, wherein the active contact area is less than 2 mm².

47. The dermatologic treatment device of claim 46, wherein the control circuitry automatically activates the source of electromagnetic radiation when contact
5 with a compliant surface is sensed.

48. The dermatologic treatment device of claim 44, wherein the sensor activation point is between zero to 1 mm distal to the window.

49. The dermatologic treatment device of claim 44, wherein the sensor activation point is between 0.1 mm to 1 mm distal to the window.

10 50. The dermatologic treatment device of claim 49, wherein the control circuitry automatically activates the source of electromagnetic radiation when contact with a compliant surface is sensed.

51. The dermatologic treatment device of claim 44, wherein each of the three or more sensors becomes active at a contact force of between about 0 oz. to about 1
15 oz.

52. The dermatologic treatment device of claim 44, wherein each of the three or more sensors becomes active at a contact force of between about 0.001 oz to about 0.1 oz.

53. The dermatologic treatment device of claim 52, wherein the control
20 circuitry automatically activates the source of electromagnetic radiation when contact with a compliant surface is sensed.

54. The dermatologic treatment device of claim 44, wherein the window has a convex outer surface.

55. The dermatologic treatment device of claim 44, wherein the window has a
25 flat outer surface.

56. The dermatologic treatment device of claim 43, wherein the control circuitry automatically activates the source of electromagnetic radiation when contact with a compliant surface is sensed.

57. A method for providing a skin contact sensor in a dermatologic treatment device having a skin contacting structure and a treatment source capable of being activated to supply a dermatologic treatment through the skin contacting structure, comprising the steps of

- 5 positioning a plurality of sensors around a periphery of the skin contacting structure; and
- inhibiting activation of the treatment source unless contact with a compliant surface is indicated by signals from the plurality of sensors.

58. The method of claim 57, further including the step of configuring the skin contacting structure so that the plurality of sensors is distal from the skin contacting structure by a predetermined amount.

59. The method of claim 58, where the configuring step includes the step of shaping the skin contacting structure to have a convex skin contacting surface.

59. The method claim 58, wherein the configuring step includes the step of shaping the skin contacting structure to have a flat skin contacting surface, and further including the step of positioning the active contact areas of the plurality of sensors to be recessed with respect to the flat skin contacting surface.

60. A method for configuring a dermatologic treatment device comprising the steps of

- 20 providing a window shaped to contact a surface and capable of heat transfer with the surface;
- controllably activating a source of electromagnetic radiation to supply a dermatologic treatment through the window;
- thermally coupling one or more heat-transfer elements to the window;
- 25 positioning three or more mechanical sensors around a periphery of the window and to have a sensor activation point distal to the window; and
- inhibiting activation of the dermatologic treatment device unless contact with a compliant surface is sensed by the three or more sensors.

61. The method of claim 60, further including the step of shaping the window so that a non-complaint surface is blocked from activating the mechanical sensors.

62. The method of claim 61, wherein the shaping step includes the step of forming a convex skin-contacting surface on the window.

63. A dermatologic treatment device comprising
a skin contacting structure;
5 a treatment source capable of being activated to supply a dermatologic treatment through the skin contacting structure;
a sensor positioned with respect to the skin contacting structure so that a non-compliant surface in contact with the skin contacting structure is unable to activate the sensor; and
10 control circuitry coupled to the sensor and configured to inhibit activation of the dermatologic treatment device unless contact with a compliant surface is sensed.

64. The dermatologic treatment device of claim 63, wherein the treatment source includes a source of electromagnetic radiation, and the skin contacting
15 structure comprises a window through which electromagnetic radiation is emitted.

65. The dermatologic treatment device of claim 64, wherein the source of electromagnetic radiation and the dermatologic treatment are configured to provide hair regrowth inhibition.

66. The dermatologic treatment device of claim 64, wherein the source of
20 electromagnetic radiation and the dermatologic treatment are configured to provide acne treatment.

67. The dermatologic treatment device of claim 64, wherein the source of electromagnetic radiation and the dermatologic treatment are configured to provide photorejuvenation.

25 68. The dermatologic treatment device of claim 63, wherein the treatment source is configured to provide a wrinkle reduction treatment.

69. The dermatologic treatment device of claim 63, wherein the control circuitry automatically activates the treatment source when contact with a compliant surface is sensed.

70. The dermatologic treatment device of claim 63, wherein the skin contacting structure has a skin contacting area, and the sensor is positioned to have a sensor activation point distal to the skin contacting area.

1 / 5

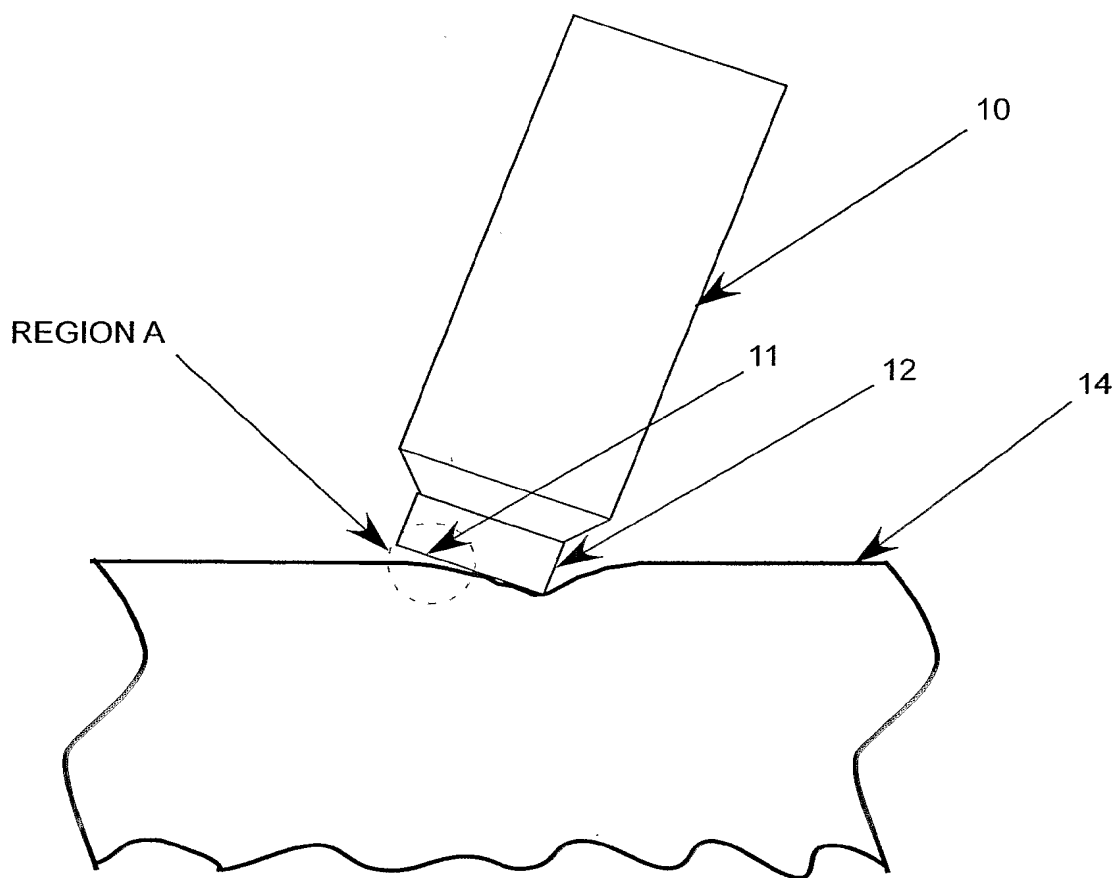


Figure 1

Figure 2B

CROSS SECTION
VIEW

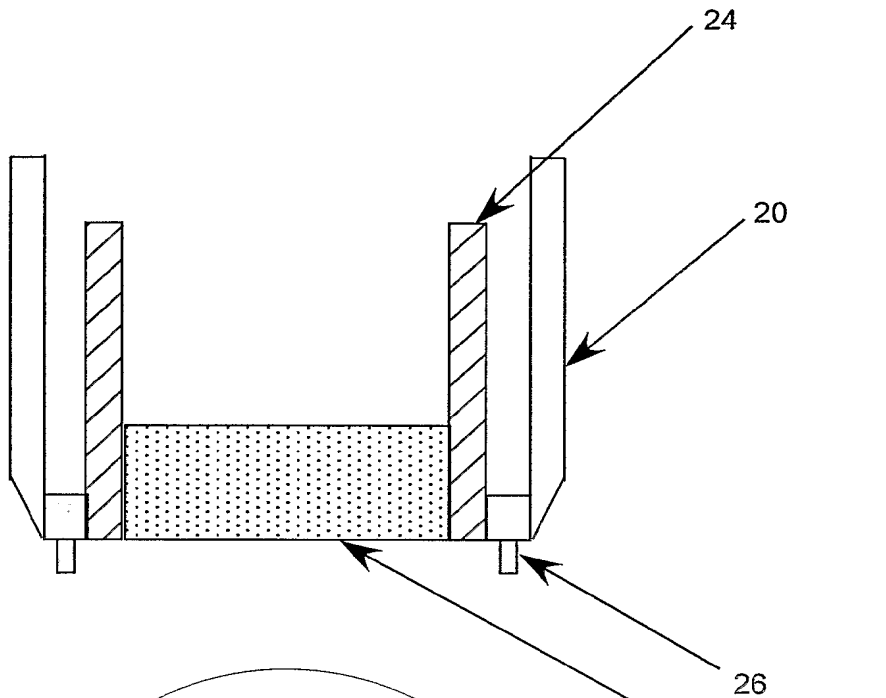


Figure 2A

PLAN VIEW

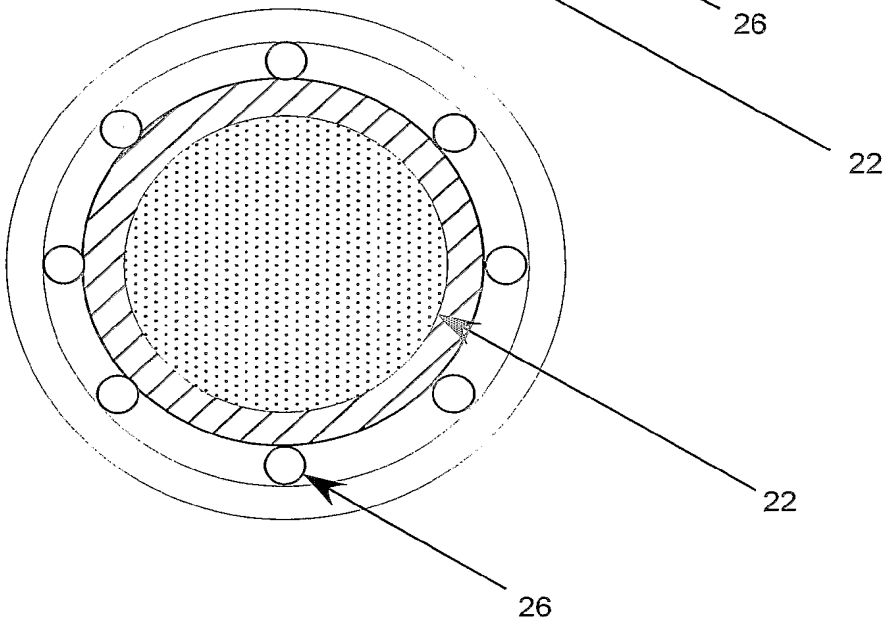


Figure 2

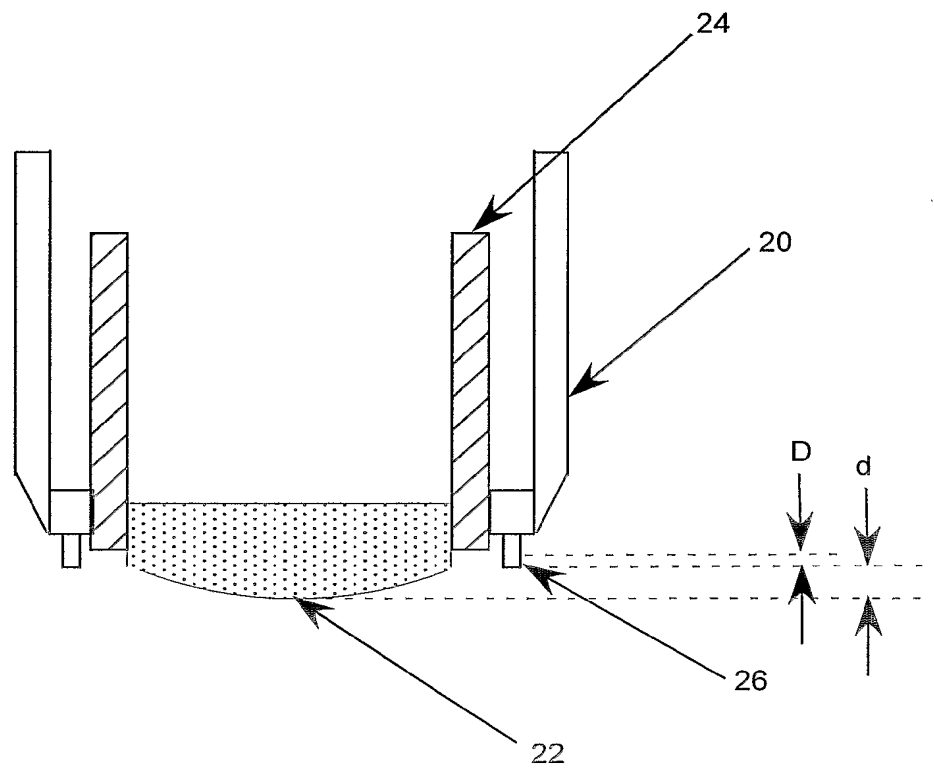


Figure 3

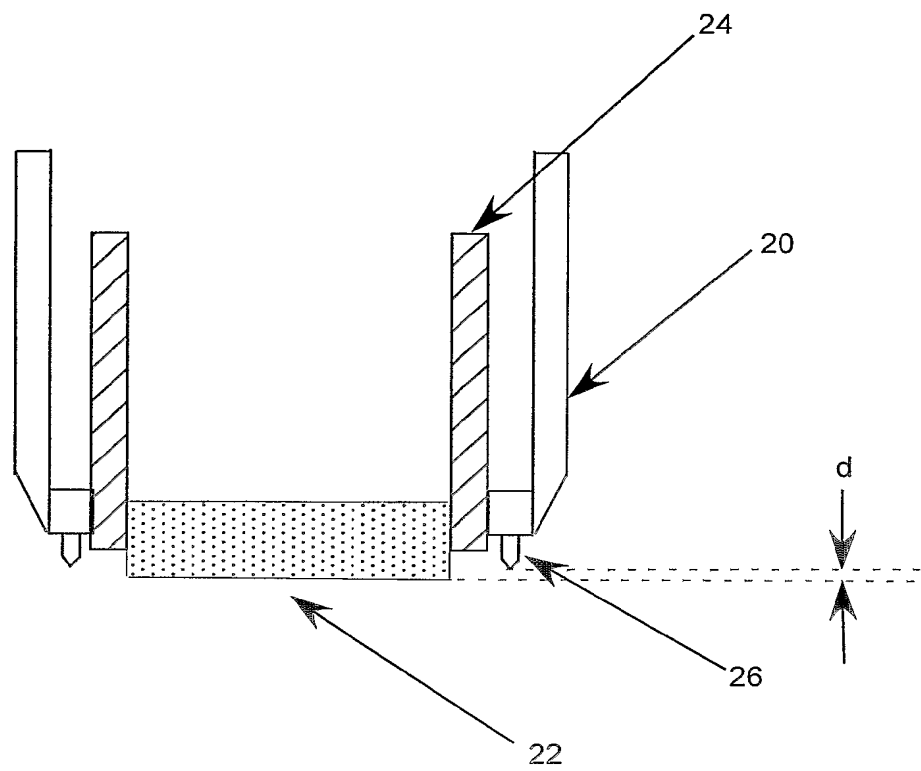


Figure 4

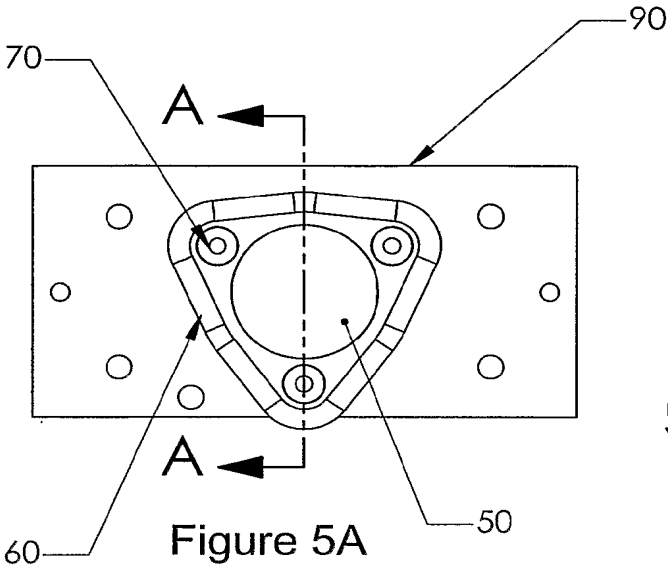


Figure 5B

SECTION A-A

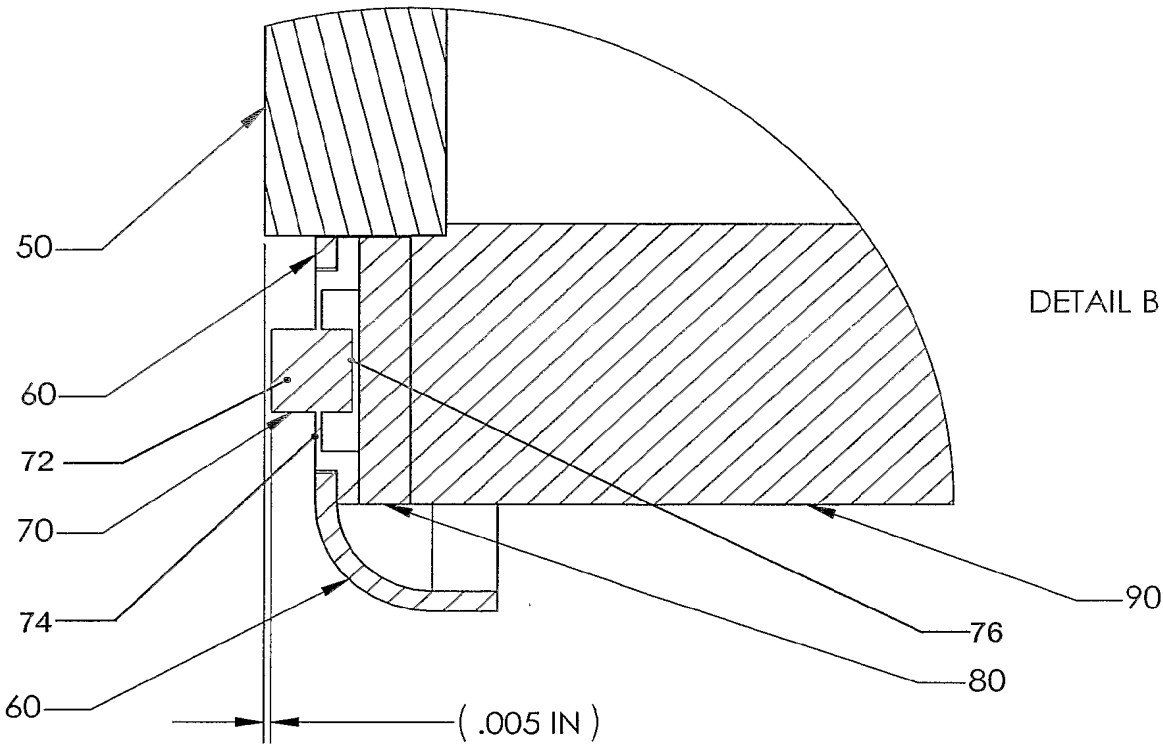
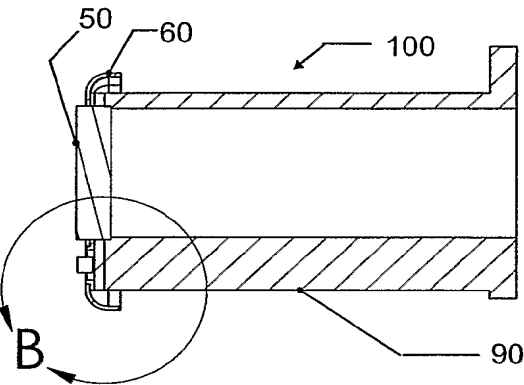


Figure 5C

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- (71) Applicant (for all designated States except US): **THE GENERAL HOSPITAL CORPORATION** [US/US]; 55 Fruit Street, Boston, MA 02114 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **MANSTEIN, Dieter** [DE/US]; 1 Longfellow Place, #2624, Boston, MA 02114 (US). **ANDERSON, Richard** [US/US]; 399 Marrett Road, Lexington, MA 02421 (US).
- (74) Agent: **ABELEV, Gary**; Baker Botts L.L.P., 30 Rockefeller Plaza, New York, NY 10112-4498 (US).

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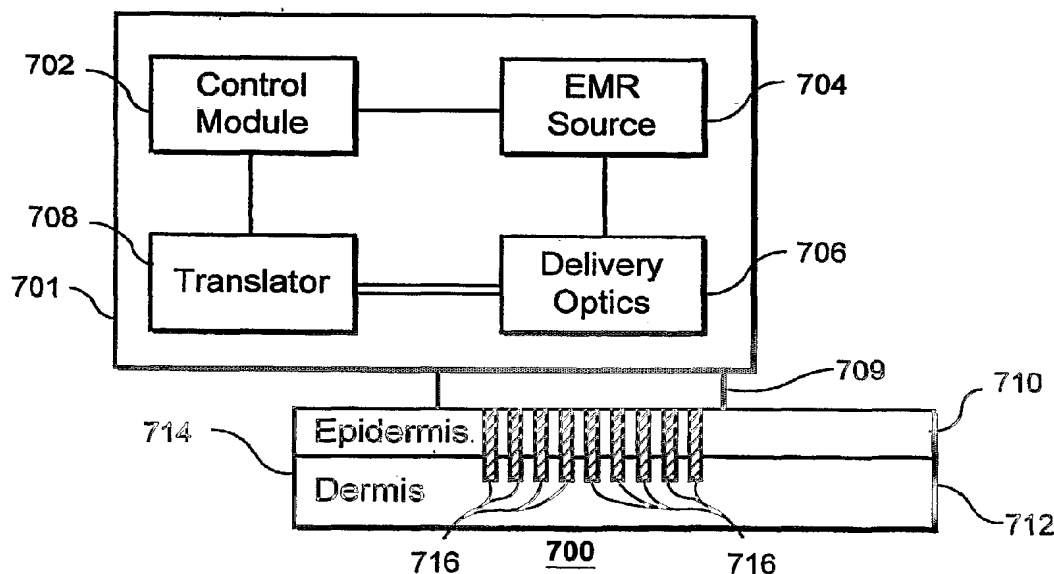
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(54) Title: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND FRACTIONAL SKIN RESURFACING



(57) Abstract: A system and method for performing fractional resurfacing of a target area of skin using electromagnetic radiation are provided. An electromagnetic radiation is generated by an electromagnetic radiation source. The electromagnetic radiation is caused to be applied to a particular portion of a target area of skin. The electromagnetic radiation can be impeded from affecting another portion of the target area of the skin by a mask. Alternatively, the electromagnetic radiation may be applied to portions of the target area of the skin, other than the particular portion.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND FRACTIONAL SKIN RESURFACING

SPECIFICATION

5 CROSS REFERENCE TO RELATED APPLICATIONS

The present application claims priority from U.S. Provisional Patent Application Serial No. 60/458,770 filed March 27, 2003, the entire disclosure of which is incorporated herein by reference.

10 BACKGROUND OF THE INVENTION

1. Field Of The Invention

The present invention relates to methods and apparatus that use electromagnetic radiation for dermatological treatment and, more particularly to a method and apparatus that use optical radiation to ablate or damage a target area of skin surface for dermatological treatment, which skin surface includes the epidermis and parts of the dermis as the objective or side effect of the desired treatment.

2. Background Art

There is an increasing demand for repair of or improvement to skin defects, which can be induced by aging, sun exposure, dermatological diseases, traumatic effects, and the like. Many treatments which use electromagnetic radiation have been used to improve skin defects by inducing a thermal injury to the skin, which results in a complex wound healing response of the skin. This leads to a biological repair of the injured skin.

Various techniques providing this objective have been introduced in recent years. The different techniques can be generally categorized in two groups of treatment modalities: ablative laser skin resurfacing ("LSR") and non-ablative collagen remodeling ("NCR"). The first group of treatment modalities, i.e., LSR, includes causing thermal damage to the epidermis and/or dermis, while the second group, i.e., NCR, is designed to spare thermal damage of the epidermis.

LSR with pulsed CO₂ or Er:YAG lasers, which may be referred to in the art as laser resurfacing or ablative resurfacing, is considered to be an effective treatment option for signs of photo aged skin, chronically aged skin, scars, superficial

pigmented lesions, stretch marks, and superficial skin lesions. However, patients may experience major drawbacks after each LSR treatment, including edema, oozing, and burning discomfort during first fourteen (14) days after treatment. These major drawbacks can be unacceptable for many patients. A further problem with LSR procedures is that the procedures are relatively painful and therefore generally require an application of a significant amount of analgesia. While LSR of relatively small areas can be performed under local anesthesia provided by injection of an anestheticum, LSR of relatively large areas is frequently performed under general anesthesia or after nerve blockade by multiple injections of anesthetic.

Any LSR treatment results in thermal skin damage to the treatment area of the skin surface, including the epidermis and/or the dermis. LSR treatment with pulsed CO₂ lasers is particularly aggressive, causing thermal skin damage to the epidermis and at least to the superficial dermis. Following LSR treatment using CO₂ lasers, a high incidence of complications can occur, including persistent erythema, hyperpigmentation, hypopigmentation, scarring, and infection (e.g., infection with Herpes simplex virus). LSR treatment with the Er:YAG laser has been introduced as a more gentle alternative to the CO₂ laser, due to the lesser penetration depth of the Er:YAG pulsed laser. Using the Er:YAG laser results in a thinner zone of thermal injury within the residual tissue of the target area of the skin. However, LSR that uses the Er:YAG laser produces side effects similar to those made by LSR that uses the CO₂ laser within the first days after treatment.

A limitation of LSR using CO₂ or Er:YAG lasers is that ablative laser resurfacing generally can not be performed on the patients with dark complexions. The removal of pigmented epidermis tissue can cause severe cosmetic disfigurement to patients with a dark complexion, which may last from several weeks up to years, which is considered by most patients and physicians to be unacceptable. Another limitation of LSR is that ablative resurfacing in areas other than the face generally have a greater risk of scarring. LSR procedures in areas other than the face result in an increased incidence of an unacceptable scar formation because the recovery from skin injury within these areas is not very effective.

In an attempt to overcome the problems associated with LSR procedures, a group of NCR techniques has emerged. These techniques are variously referred to in the art as non-ablative resurfacing, non-ablative subsurfacing, or non-ablative skin remodeling. NCR techniques generally utilize non-ablative lasers,

flashlamps, or radio frequency current to damage dermal tissue while sparing damage to the epidermal tissue. The concept behind NCR techniques is that the thermal damage of only the dermal tissues is thought to induce wound healing which results in a biological repair and a formation of new dermal collagen. This type of wound healing can result in a decrease of photoaging related structural damage. Avoiding epidermal damage in NCR techniques decreases the severity and duration of treatment related side effects. In particular, post procedural oozing, crusting, pigmentary changes and incidence of infections due to prolonged loss of the epidermal barrier function can usually be avoided by using the NCR techniques.

Various strategies are presently applied using nonablative lasers to achieve damage to the dermis while sparing the epidermis. Nonablative lasers used in NCR procedures have a deeper dermal penetration depth as compared to ablative lasers used in LSR procedures. Wavelengths in the near infrared spectrum can be used. These wavelengths cause the non-ablative laser to have a deeper penetration depth than the very superficially-absorbed ablative Er:YAG and CO₂ lasers. The dermal damage is achieved by a combination of proper wavelength and superficial skin cooling, or by focusing a laser into the dermis with a high numerical aperture optic in combination with superficial skin cooling. While it has been demonstrated that these techniques can assist in avoiding epidermal damage, one of the major drawbacks of these techniques is their limited efficacies. The improvement of photoaged skin or scars after the treatment with NCR techniques is significantly smaller than the improvements found when LSR ablative techniques are utilized. Even after multiple treatments, the clinical improvement is often far below the patient's expectations. In addition, clinical improvement is usually several months delayed after a series of treatment procedures.

Another limitation of NCR procedures relates to the breadth of acceptable treatment parameters for safe and effective treatment of dermatological disorders. The NCR procedures generally rely on an optimum coordination of laser energy and cooling parameters, which can result in an unwanted temperature profile within the skin leading to either no therapeutic effect or scar formation due to the overheating of a relatively large volume of the tissue.

Yet another problem of non-ablative procedures relates to the sparing of the epidermis. While sparing the epidermis is advantageous in order to decrease the side effects related to complete removal of the epidermis, several applications of

NCR procedures may benefit from at least partial removal of epidermal structures. For example, photoinduced skin aging manifests not only by the dermal alterations, but also by epidermal alterations.

A further problem of both ablative and nonablative resurfacing is that the role of keratinocytes in the wound healing response is not capitalized upon. Keratinocyte plays an active role in the wound healing response by releasing cytokines when the keratinocyte is damaged. During traditional ablative resurfacing procedures, the keratinocytes are removed from the skin along with the epidermis, thereby removing them from the healing process altogether. On the other hand, in traditional non-ablative procedures, the keratinocytes, which are located in the epidermis, are not damaged, therefore they do not release cytokines to aid in the healing process.

Another major problem with all LSR and NCR techniques now used is the appearance of visible spots and/or edges after treatment due to inflammation, pigmentation, or texture changes, corresponding to the sites of treatment. Devices for LSR and NCR produce macroscopic (easily seen) exposure areas. For example, laser exposure spot diameters typically vary from about 1 to 10 mm, and NCR exposure spot diameters from about 3 to 50 mm. Some devices, such as intense pulsed light devices, leave "boxes" of skin response due to rectangular output patterns on the skin. Patients do not like such spot or box patterns, easily seen as red, brown or white areas ranging from on the order of millimeters to centimeters in size, which remain for days or even years after treatment.

Therefore, there is a need to provide a procedure and apparatus that combine safe and effective treatment for improvement of dermatological disorders with minimum side effects, such as intra procedural discomfort, post procedural discomfort, lengthy healing time, and post procedural infection.

SUMMARY OF THE INVENTION

It is therefore one of the objects of the present invention to provide an apparatus and method that combines safe and effective treatment for an improvement of dermatological disorders with minimum side effects. Another object of the present invention is to provide an apparatus and method that cause thermal skin damage to only a fraction of a target area of skin.

These and other objects can be achieved with the exemplary embodiment of the apparatus and method according to the present invention, in which portions of a target area to be subjected to irradiation are masked. The exemplary apparatus can include at least one shielding member configured to mask at least one portion of a target area of skin from electromagnetic radiation, in which the shielding members are formed such that a minimal amount of electromagnetic radiation is reflected back towards an electromagnetic radiation source.

In another advantageous embodiment of the present invention, electromagnetic radiation can be generated by an electromagnetic radiation source, thus causing the electromagnetic radiation to be applied to a target area of the skin. At least one portion of the target area of the skin is then masked from the electromagnetic radiation using a mask.

In yet another advantageous embodiment of the present invention, an apparatus and method for treating dermatological conditions is provided. In particular, a delivery module and translator are utilized. The delivery module is configured to direct electromagnetic radiation generated by an electromagnetic radiation source to a predetermined area within a target area of skin, wherein the predetermined area is located in a location relative to the delivery module, and wherein the electromagnetic radiation is adapted to cause thermal damage to epidermal tissue and dermal tissue of the predetermined area within the target area of the skin. The translator is capable of moving the delivery module, such that the delivery module targets a plurality of spatially separated individual exposure areas of the predetermined area.

In a further advantageous embodiment of the present invention, the electromagnetic radiation can be applied to a first individual exposure area of the target area of the skin. The electromagnetic radiation can then be applied to a second individual exposure area of the target area of the skin, which is separated from the first individual exposure area by a non-irradiated skin section.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention and its advantages, reference is now made to the following description, taken in conjunction with the accompanying drawings, in which:

Figs. 1A – 1C show progressive illustrations of a first exemplary embodiment of a fractional resurfacing system for conducting various dermatological treatments at various stages of use according to the present invention;

Fig. 2 shows a top view of a first exemplary embodiment of a mask
5 according to the present invention;

Fig. 3 shows a cross-sectional view of the mask of Fig. 2;

Fig. 4 shows a top view of a second exemplary embodiment of the mask according to the present invention;

Fig. 5 shows a cross-sectional view of the mask of Fig. 4;

Fig. 6 shows a cross-sectional view of another variant of the mask of Fig. 4;

Figs. 7A and 7B show progressive illustrations of a second exemplary embodiment of the fractional resurfacing system for conducting various dermatological treatments at various stages of use according to the present invention;

Fig. 8 shows a top view of small individual exposure areas created by the fractional resurfacing system of Figs. 7A and 7B; and

Fig. 9 shows an exemplary embodiment of a system for monitoring the location of the fractional resurfacing system of Figs. 7A and 7B.

Throughout the drawings, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components, or portions of the illustrated embodiments. Moreover, while the present invention will now be described in detail with reference to the Figures, it is done so in connection with the illustrative embodiments.

25 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figs. 1A – 9 illustrate various embodiments of a method and apparatus for fractional resurfacing of a target area of skin. Generally, the exemplary methods and apparatus deliver an electromagnetic radiation to the patient's skin defined by various patterns, so as to induce thermal injury of the skin surface corresponding to such patterns and involving only a fraction of the targeted surface area of the skin. Such technique combines the efficacy of ablative resurfacing procedures with the minimal side effects of non-ablative procedures. The delivery of the electromagnetic radiation to the skin in a predetermined pattern is achieved by either masking parts of the target area of the skin surface in order to protect the masked parts of the skin

surface from the electromagnetic radiation, or by utilizing a light beam of relatively small diameter which is scanned across the skin surface by various means in order to generate a specific pattern for affecting superficial thermal skin injury.

Fractional resurfacing is defined as the controlled ablation, removal,
5 destruction, damage or stimulation of multiple small (generally less than 1 mm) individual exposure areas of skin tissue with intervening spared areas of skin tissue, performed as a treatment to improve the skin. The individual exposure areas may be oval, circular, arced and/or linear in shape. The spatial scale of fractional resurfacing is chosen to avoid the appearance of various spots or boxes on a macroscopic scale,
10 while still providing effective treatment because the multiple small areas can be exposed to greater than a minimal stimulus. For example, removal or photothermal destruction of thousands of 0.1 mm diameter individual exposure areas, spaced 0.2 mm apart, and extending into the skin up to a depth of 0.5 mm, is well tolerated and produces effective improvement of photoaging, without apparent spots and with rapid
15 healing. Spared skin between the individual exposure areas rapidly initiates a wound healing response, which is better tolerated than conventional LSR.

During the exemplary fractional resurfacing procedure of the present invention, certain portions of the target area remain undamaged, thereby preserving keratinocytes and melanocytes, which serve as a pool of undamaged cells to promote
20 reepithelialization. This procedure differs from the traditional resurfacing procedures, such that the entirety of the target area is damaged. In traditional resurfacing procedures, reepithelialization is generally initiated from the depth of an undamaged follicular epithelium. Because the traditional procedures remove the entire epithelium, an important factor for the time of reepithelialization is the density of
25 follicles. The vellus hair density of the face (439 hairs/cm²) of the subject is significantly higher than on the back of the subject (85 hairs/cm²). Therefore, the face of the subject, generally experiences better and faster reepithelization in comparison to other body areas with a lower hair density.

The resurfacing of the dark pigmented skin is currently not very
30 frequently performed because of the prolonged repigmentation process. The fractional resurfacing technique improves the repigmentation process but, melanocytes do not migrate well. By sparing certain portions of the target area of the skin, the travel distance of melanocytes can be decreased, thereby reducing the repigmentation time and allowing the resurfacing of all skin types.

Figs. 1A – 1C illustrate a progressive use of a first exemplary embodiment of a fractional resurfacing system 100 for conducting various dermatological treatments using electromagnetic radiation (“EMR”) and generating a superficial pattern of skin damage of a target area by using a mask according to the present invention. The system 100 may be used for collagen remodeling, removal of unwanted pigment or tattoo, and/or other dermatological applications. As shown in Figs. 1A-1C, the system 100 includes a case 101, a control module 102, an EMR source 104, delivery optics 106 and a mask 108. The case 101 contains the control module 102, the EMR source 104, and the delivery optics 106. An aperture is provided through a sidewall of the case 101. The mask 108 is placed in registration with the aperture formed through the sidewall of the case 101. By placing the mask 108 in registration with the aperture of the case 101, the focal length of the EMR emitted by the delivery optics 106 is fixed, and can be configured such that it does not impact the side of the mask 108, so as to cause injuries to the operator of the fractional ablation system 100. The control module 102 is in communication with the EMR source 104, which in turn is operatively connected to the delivery optics 106.

In one exemplary variant of the present invention, the control module 102 can be in wireless communication with the EMR source 104. In another variant, the control module 102 may be in wired communication with the EMR source 104. In another exemplary variant of the present invention, the control module 102 can be located outside of the case 101. In another variant, the EMR source 104 is located outside of the case 101. In still another variant, the control module 102 and the EMR source 104 are located outside of the case 101. It is also possible that the mask 108 is not connected to the case 101.

The control module 102 provides application specific settings to the EMR source 104. The EMR source 104 receives these settings, and generates EMR based on these settings. The settings can control the wavelength of the EMR, the energy delivered to the skin, the power delivered to the skin, the pulse duration for each EMR pulse, the fluence of the EMR delivered to the skin, the number of EMR pulses, the delay between individual EMR pulses, the beam profile of the EMR, and the size of the area within the mask exposed to EMR. The energy produced by the EMR source 104 can be an optical radiation, which is focused, collimated and/or directed by the delivery optics 106 to the mask 108. The mask 108 can be placed on a target area of a patient’s skin, and may provide a damage pattern on the target area of

the skin with a fill factor in the range from 0.1% to 90%. The fill factor is the percentage of the target area exposed to the EMR that is emitted by the EMR source 106.

5 In one exemplary embodiment, the EMR source 106 is one of a laser, a flashlamp, a tungsten lamp, a diode, a diode array, and the like. In another exemplary embodiment, the EMR source 106 is one of a CO₂ laser and a Er:YAG laser.

Prior to being used in a dermatological treatment, the system 100 shown in Fig. 1A can be configured by a user. For example, the user may interface with the control module 102 in order to specify the specific settings usable for a particular procedure. The user may specify the wavelength of the EMR, the energy delivered to the skin, the power delivered to the skin, the pulse duration for each EMR pulse, the fluence of the EMR delivered to the skin, the number of EMR pulses, the delay between individual EMR pulses, the beam profile of the EMR, and the size of the area within the mask exposed to EMR. The EMR source 104 may be set to produce a collimated pulsed EMR irradiation with a wavelength ranging from 400 to 11,000 nm, and preferably near 3.0 μm when using an Er:YAG laser and near 10.6 μm when using a CO₂ laser as the EMR source. The collimated pulsed EMR irradiation may be applied which has a pulse duration in the range of 1 μs to 10 s, preferably in the range of 100 μs to 100 ms, and more preferably in the range of 0.1 ms to 10 ms, and fluence in the range from 0.01 to 100 J/cm², and preferably in the range from 1 to 10 J/cm². The applied EMR should be able to achieve at least a temperature rise within the exposed areas of the skin that is sufficient to cause thermal damage to the epidermis 110 and/or the dermis 112. The peak temperature sufficient to cause thermal damage in the exposed tissues is time dependant and at least in the range of 45° C to 100° C. For exposure times in the range of 0.1 ms to 10 ms the minimum temperature rise required to cause thermal damage is in the range of approximately 60° C to 100° C. The depth of thermal damage can be adjusted by proper choice of wavelength, fluence per pulse and number of pulses.

During the dermatological treatment, the system 100 produces EMR 120 which is directed to the target area of the skin 114, as shown in Fig. 1B. The EMR 120 may be pulsed multiple times to create the appropriate affect and irradiation in the target area of the skin 114.

After the dermatological treatment is completed, the target area of the skin 114 is likely damaged in specific places. The application of the EMR 120 creates a prearranged thermal skin damage 130 in an epidermal tissue 110 and the dermal tissue 112. It should be noted that the thermal skin damage 130 extends through the epidermal tissue 110 and into the dermal tissue 112 only to a predetermined depth. The mask 108 controls in a location where the thermal skin damage 130 is created. The thermal skin damage 130 generally accounts for only 0.1% to 90% of the skin surface area in the target area. A fill factor is defined as the ratio of surface area of the target area of skin thermally damaged by EMR to surface area of the target area of the skin.

In an exemplary embodiment of the present invention, the thermal skin damage 130 may extend through the epidermal tissue 110 and through the entirety of the dermal tissue 112. In another exemplary embodiment of the present invention, the thermal skin damage 130 may occur principally in the dermal tissue 112 and minor skin damage may occur in the epidermal tissue 110. It should be noted that it is possible that the penetration depths of each of the micro areas of the thermal skin damage 130 may be different from one another or same as one another. This may be because pigment removal or dermal removal can be separately regulated by varying the density of the micro-damaged areas for either the deeper or superficial damages, e.g., dermal remodeling and pigment adjustment, respectively.

Fig. 2 illustrates a top view of a first exemplary embodiment of the mask 108 according to the present invention. The mask 108 includes shielding structured 202. The diameter of the mask 108 should preferably be matched to greater than the size of the diameter of the target area. The target area is defined as the area targeted by the collimated EMR emitted by the EMR source 104, which can be in the range 1 - 100 mm in diameter, preferably within the range of 5 to 20 mm. This diameter of most of the currently commercially available CO₂ and Er:YAG laser systems can match the diameter of the exposed area. The width of shielding structures 202 within the mask 108 should be in the range of 50 to 300 μ m. The width of the apertures of the mask 108 that are formed by the shielding structures should be in the range of 10 - 1000 μ m, and preferably in the range of 50 to 300 μ m. The shielding-exposure ratio surface area covered by the of shielding structures 202 to the surface area exposed by the apertures effects the clinical efficacy and provides

side effects of the dermatological treatment. This also determines the fill factor and the pattern of the thermal damage of the skin. The depth of thermal damage is determined by the number of pulses, the fluence of the EMR and the wavelength of the EMR. The shielding-exposure ratio of the mask 108 will vary for different
5 dermatological treatments, particular patient needs, particular patient indications, skin types and body areas.

The mask 108 may have a large shielding-exposure ratio at the edge of the mask 108 to generate a transition zone at the edge of resurfaced area. This technique is called "feathering." It avoids a sharp macroscopically visible
10 demarcation between treated and untreated areas. In another preferred embodiment, a mask may be used that has a large shielding-exposure ratio at the edge of a conventionally resurfaced area to generate a transition zone.

The surface of the mask 108 should preferably have a minimal absorption at the wavelength generated by the EMR source 104 for the particular
15 dermatological process. Such absorption can decrease the undesirable heating of the mask 108. The mask 108 may be coated by a metal material for affectuating a minimal absorption of the EMR. The design of the shielding structures 202 of the mask 108, a cross-section A-A of which is shown in Fig. 3; generally takes into consideration safety aspects, including a back-reflected EMR in order to avoid EMR
20 inflicted accidents. The shielding structures 202 are shaped in a peaked manner to minimize the amount of back reflected EMR. Also, with the mask 108 being connected to the case 101 the distance between the delivery optics 106 and the mask 108 is fixed, thereby minimizing the chances that EMR would be reflected back towards the user by hitting the edge of the mask 108. Additionally, the microstructure
25 of the mask 108 can have a periodicity preferably in the range of the wavelength of the EMR emitted by the delivery optics 106. This configuration can diffuse the collimated EMR emitted by the delivery optics 106 into a highly scattered beam so as to decrease the risk of EMR-related accidents.

In one exemplary embodiment, the metal coating of the mask 108 may
30 be composed of gold, silver, or copper materials, or the like. In another exemplary embodiment, the microstructure of the surface of the mask 108 may have a periodicity in the range of the wavelength of the EMR emitted by the delivery optics 106.

The mask 108 may also have a configuration so as to provide effective skin cooling during the exposure thereof with the EMR radiation. Skin cooling

provides significant anesthetic effects, and has other advantages related to the pattern induced by the EMR radiation. The mask 108 can be cooled prior to the beginning of the dermatological procedure, during the procedure by spraying an evaporative agent or a precooled liquid onto the mask 108 between the successive EMR pulses, or
5 during the procedure by introducing a cool or cold liquid into microchannels 302 (shown in Fig. 3) running through the mask 108. The cooling of the mask 108 has a secondary advantage in that such cooling of the mask 108 decreases the rate of the EMR absorption by the mask 108, as the rate of the EMR absorption by the metals increases with the increasing temperature.

10 In order to provide skin cooling as described above, the temperature of the mask 108 should be in the range of 37° C to -20° C, and preferably 10° C to -4° C. The mask 108 can both protect and cool the portions of the skin surface that are not exposed to EMR emitted by the EMR source 104. In addition to cooling and shielding portions of the skin surface, the mask 108 allows the debris ejected during
15 ablative procedures to escape, and thereby not interfere with the beam delivery for successive pulses. For example, the areas that are not exposed to the laser are being cooled by the mask 108, i.e., the areas that are provided between the affected areas. In another exemplary embodiment, all areas (i.e., both the affected and nonaffected areas) are cooled to provide anesthesia, and to reduce over-damaging the superficial
20 levels of the damaged areas.

Fig. 3 illustrates a cross-section A-A of the mask 108 of Fig. 2. The cross-section A-A shows the microchannels 302 that run through at least the shielding structures 202 of the mask 108. A cooling agent, e.g., either a liquid or gas, may circulate through these microchannels 302 during a dermatological procedure, thereby
25 removing heat from the protected skin and the mask 108 itself.

Fig. 4 illustrates a top view of a second embodiment of the mask 400 according to the present invention. The mask 400 differs from the mask 108 only in the layout and design of the shielding structures 402. The details of the mask 400 are in all other respects substantially similar to those of the mask 108. The shielding
30 structures 402 are cylindrical in shape, as indicated in cut-away cross-sections B-B and C-C, shown in Figs. 5 and 6, respectively. The shielding structures 402 of the mask 400 contain microchannels 502 and 602, which are capable of carrying a cooled liquid or gas so as to cool the mask 400 and the masked portions of the target area of

the skin. The microchannels 502, 602 intersect at the intersection of the shielding structures 402.

In an exemplary embodiment of the present invention, the microstructures 502, 602 are not required to intersect at the intersection of the shielding structures 402.

In an exemplary embodiment of the present invention, the mask 108 is an ablative mask. An ablative mask includes multiple sections having various thicknesses. Prior to a procedure, the ablative mask is attached to the skin with an adhesive. During the procedure having multiple EMR pulses, the ablative mask is ablated, such that the thickness of each of the multiple sections is diminished, potentially gradually exposing different areas of the skin to the EMR pulses. The ablative mask can be composed of various materials including polymer materials. The ablative mask can be easily produced by imprinting a pattern therein.

A particular dermatological treatment, i.e., the removal of tattoos, shall be described in further detail. Tattoo removal may be performed with a combination of an ablative EMR and the mask 108. In particular, utilizing the CO₂ laser and/or the Er:YAG laser may be appropriate for this application. During this dermatological procedure, the tattoo can be exposed to ablative EMR radiation with the mask 108 providing a fill factor of the target area in the range of 10 to 90%, and preferably in the range of 25 to 70%. Preferably, the mask 108 is applied under pressure to the skin, which minimizes the blood flow during the procedure. Limiting the blood flow during the procedure allows a deeper ablation of the skin surface before blood can interfere with the EMR radiation, thereby limiting the ablation depth. Multiple pulses of ablative EMR radiation can be applied to the individual areas of the tattoo until the desired ablation depth is reached. The desired ablation depth can be in the range of 100 μ m to 5 mm. This exemplary procedure can cause a specific fraction of the tattoo that is controlled by the mask 108 to be immediately ablated. Wound healing may be enhanced because only a fraction of the surface is ablated.

The removal of tattoos utilizing fractional resurfacing may be augmented using a short pulsed EMR, preferentially absorbed by the tattoo particles either before or after the application of the fractional resurfacing. In a short pulsed-laser application, the laser may be pulsed for short periods of time, preferably for less than 1 μ s in duration. The EMR source used in this type of procedure can preferably be a Q-switched ruby laser, a Nd:YAG laser, a KTP laser and/or an Alexandrite laser.

The objective of this procedure is to release the pigment within areas that are not exposed to fractional resurfacing ablation. The released pigment particles may drain in the ablated channels, and can be flushed from the area after the procedure by the blood resident in the target area and/or an external rinsing agent, e.g., saline. Several
5 such procedures may be utilized until the desired clearance of the tattoo has occurred.

As an alternative to the fractional resurfacing using a mask, a second embodiment of a fractional resurfacing system 700, as shown as the progressive use thereof in Figs. 7A – 7B, can be used. The system 700 can include a case 701, a control module 702, an electromagnetic radiation (“EMR”) source 704, delivery
10 optics 706, an x-y translator 708 and an optically transparent plate 709. The case 701 may contain the control module 702, the EMR source 704, the delivery optics 706 and the translator 708. As with the system 100, an aperture may be formed through a sidewall of the case 701. The optically transparent plate 709 may be placed in registration with the aperture that is formed through the sidewall of the case 701.
15 Placing the plate 709 in registration with the aperture formed through the sidewall of the case 701 seals the system 700, which contains sophisticated translation mechanisms, e.g., the delivery optics 706 and the translator 708. The control module 702 is in communication with the translator 708 and the EMR source 704, and the EMR source 704 is operatively connected to the delivery optics 706.

20 In one exemplary variant of the present invention, the control module 702 can be located outside of the case 701. In another exemplary variant, the EMR source 704 is located outside of the case 701. In still another variant, the control module 702 and the EMR source 704 are located outside of the case 701.

The control module 702 provides application specific settings to the
25 EMR source 704, and controls the x-y translator 708. The EMR source 704 receives these settings, and generates EMR based on these settings. The settings can control the wavelength of the energy produced, the intensity of the energy produced, the fluence of the energy produced, the duration of the dermatological procedure, the pulse length of each of the EMR pulses administered during the procedure, the spatial
30 distance between individual exposure areas 716 (shown in Fig. 8), the shape of individual exposure areas 716, the pattern defined by individual exposure areas 716, and the fill factor of the target area. It should be noted that the thermal skin damage caused to individual exposure areas 716 extends through the epidermal tissue 710 and into the dermal tissue 712 only to a predetermined depth. The EMR source 704 can

be a laser or other light source. The EMR produced by the EMR source 704 can be delivered through a fiber, waveguide or mirrors if the source is located outside the delivery optics 706. Alternatively, if the EMR source 704 is located in a close vicinity to the skin 714, the EMR source 704 produces the EMR directly to the delivery optics 706. The energy produced by the EMR source 704 may be focused and/or directed by focusing optics in the delivery optics 706 to one of the individual exposure areas 716, shown in Fig. 8. Each of the individual exposure areas 716 are located within the target area of the skin 714, and are relatively small compared to the target area of the skin 714. The target area of the skin 714 can generally be 1 cm² in size and each of the individual exposure areas 716 may be 100 μm in diameter.

In an exemplary embodiment of the present invention, the optics of the delivery optics 706 may contain a beam collimator or focusing optics. In another exemplary embodiment of the present invention, the thermal skin damage caused to individual exposure areas 716 may extend through the epidermal tissue 710 and through the entirety of the dermal tissue 712. In another exemplary embodiment of the present invention, the thermal skin damage caused to individual exposure areas 716 may principally occur in the dermal tissue 712 and only minor thermal damage may occur in the epidermal tissue 710. It should be noted that it is possible that the penetration depths of each of the micro areas of the thermal skin damage caused to individual exposure areas 716 may be different from one another or same as one another. This may be because pigment removal or dermal removal can be separately regulated by varying the density of the micro-damaged areas for either the deeper or superficial damages, e.g., dermal remodeling and pigment adjustment, respectively. In a further exemplary embodiment of the present invention, the predetermined depth of the thermal skin damage caused to individual exposure areas 716 is approximately 300 μm.

Prior to use in a dermatological treatment and similarly to the use of system 100, the system 700, as shown in Fig. 7A, can be configured by a user. In particular, the user interfaces with the control module 702 in order to specify the specific settings to be used for a particular procedure. The user may specify the desired damage pattern, the wavelength of the energy produced by the EMR source 704, the intensity of the energy produced, the fluence of the energy produced, the length of time the treatment will take and the pulse duration of the EMR source 704.

During the treatment, the translator 708 moves the delivery optics 706 across sequential portions of the target area of the skin 714 in order to treat the entire target area. The target area is treated when the system 700 delivers EMR to individual exposure areas 716 of the target area. The individual exposure areas 716 may be
5 targeted serially and/or in parallel. When one of the portions of the target area has been completely treated, the system 700 is moved to the next portion of the target area. For example, the system 700 is moved at the completion of irradiation of each portion of the target area until the desired skin surface damage pattern is achieved for the entire area. The system 700 can be moved using discrete movements from one
10 sequential portion to the next, i.e., stamping mode, or using continuous movement across the skin surface, i.e., continuous scanning mode. In either case, the movement of the delivery optics 706, driven by the translator 708, is controlled by the control unit 702 and likely matched with the movement of the system 700 by the operator (or the user) in order to provide the desired surface damage pattern to the target area of
15 the skin 714.

In an exemplary embodiment of the present invention, the system 700, while operating in the continuous scanning mode, can deliver EMR to a particular individual exposure area 716, then, after exposure of such area 716, translate along the skin of the target area, and thereafter deliver a further EMR to another individual
20 exposure area 716 separated from the previous particular individual exposure area 716 by non-irradiated region. In another exemplary embodiment of the present invention, the system 700, while operating in the continuous scanning mode, can deliver EMR to a particular group of individual exposure areas 716, for example the top row of individual exposure areas 716 (shown in Fig. 8), then, after exposure of such areas
25 716, translate along the skin of the target area, and deliver a further EMR to another group of individual exposure areas 716, for example the second row of individual exposure areas 716 (shown in Fig. 8), separated from the particular group of individual exposure areas 716 by non-irradiated areas.

In an exemplary embodiment of the present invention, the system 700
30 includes a position sensor, which is in communication with the control module 702. The position sensor is capable of sensing the relative velocity as between the skin 114 and the case 701. The position sensor can be an optical mouse, wheels, track ball, conventional mouse, and the like.

In another exemplary embodiment of the present invention, the system 700 targets individual exposure areas 716 one at a time. Administering EMR to the individual exposure areas 716 one at a time decreases the amount of pain experienced by the subject. A time period of 50 milliseconds may be provided between each administration of EMR to each of the individual exposure areas 716. Thereby controlling the amount of pain experienced by the subject and avoiding bulk heating of the tissue targeted by the system 700. In still another exemplary embodiment of the present invention, the system 700 targets a predetermined number of individual exposure areas 716 at a time. Limiting the number of predetermined target areas 716 targeted at one time limits the amount of pain experienced by a patient. Targeting a large number of individual exposure areas 716 at one time requires targeting a collectively large area of skin, which excites many nerve endings simultaneously, therefore causing the subject a proportionally large amount of pain. Targeting fewer individual exposure areas 716 causes a subject less pain, but causes a procedure to take longer.

In a further exemplary embodiment of the present invention, the system 700 creates individual exposure areas 716 having a separation distance between each of the individual exposure areas 716 of approximately at least 125 μm and at most 500 μm , preferably, the separation distance is approximately at least 250 μm .

Before the initiation of a dermatological procedure, the optically transparent plate 709 can be brought in a direct contact with the skin surface covering the target area. The optically transparent plate 709 can be composed out of any material having good thermal conductivity, and being transparent over a broad range of the visible and near infrared spectrum. The plate 709 seals the system 700, which contains sophisticated translation mechanisms, and provides cooling to the target area of the skin 714. The plate 709 can provide cooling to the target area of the skin 714 in two ways: heat conduction and heat convection. Heat conduction transfers heat through the optically transparent plate 709 to the case 701, which provides cooling by circulating a coolant agent through the case 701 of the system 700. The entire optically transparent place 709 can also be cooled prior to application to the target area of the skin 714. Alternatively, heat convection can be utilized for this procedure. An evaporating agent sprayed onto the optical window or onto a compartment in good thermal contact with the window may also be utilized. The delivery of the

evaporating agent can be administered during the procedure between EMR pulses through a valve, which can be controlled by a thermostat with a temperature sensor at the optical plate.

5 In one embodiment, of the present invention the optically transparent plate 709 can be composed of sapphire or quartz. In another embodiment of the present invention, the system 700 can be moved multiple times over the same portion of the skin 714 until the desired fill factor is achieved. In yet another embodiment, multiple procedures can be performed to achieve the desired effect.

10 During the dermatological procedure, the EMR source 704 emits EMR having a wavelength in the range of 400 - 12,000 nm. Preferably the EMR has a wavelength in one of the following ranges: 1,300 to 1,600 nm, 1,850 to 2,100 nm, 2,300 to 3,100 nm and around 10,640 nm. Depending on the application, a single wavelength or a combination of different wavelengths may be utilized. The EMR source 704 can be a diode laser, a fiber laser, a solid state laser, a gas laser, and the
15 like. The pulse duration can range from 100 μ s to 100 ms, and preferably in the range from 500 μ s to 15 ms, and more preferably in the range from 1.5 ms to 5 ms. The energy density per pulse within an individual exposure area 716 may be in the range of 0.1 to 100J/cm², preferably 1 to 32 J/cm², and more preferably 1.5 to 3 J/cm². The energy per pulse within an individual exposure area 716 may be in the range of 1 mJ
20 and 10 mJ, and preferably 5 mJ.

In an exemplary embodiment of the present invention, the EMR source 704 is a 1.5 μ m laser system, preferably a Reliant FSR prototype, manufactured by Reliant Technologies, Palo Alto, CA, is used.

25 After the dermatological treatment is completed, the target area of the skin 714 is damaged in a specific pattern. The application of EMR creates the thermal skin damage in an epidermis 710 and a dermis 712 of the skin 714. The radiation provided by the EMR source 704 is delivered to the skin 714 within multiple small individual exposure areas 716, shown in Fig. 7B, through the delivery optics 706. The delivery optics 706 can deliver multiple individual beams across the target area of
30 the skin surface.

Fig. 8 illustrates a top view of the small individual exposure areas 716 of the epidermis. The shape of the individual exposure areas 716 may be circular (shown in Fig. 8), elliptical, rectangular, linear or irregular with a lateral diameter of

the smallest dimension in the range of 1 – 500 μm . The fill factor of the target area can be approximately 20 – 40%.

The system 700 can create multiple individual exposure areas 716 through heating, ablation, removal, photothermal coagulation, thermal necrosis and/or stimulation. The multiple areas can be exposed sequentially or simultaneously. Sequential exposure may be achieved by scanning or moving an energy source which may be either pulsed, shuttered or continuous. Simultaneous exposure can be achieved, for example, by an array of sources or a multi-array of lenses. The array of sources may be a uni-dimensional array, a bi-dimensional array or the like. The array can be moved relative to the skin, and one or multiple passes of treatment can be performed in a target area.

Fig. 9 illustrates an exemplary embodiment of a monitoring system 900 according to the present invention. The monitoring system 900 tracks the movement of the system 700, and feeds such positional information to the control module 702. The control module 702 utilizes this information to appropriately instruct the translator 708 to position the delivery optics 706, such that the appropriate damage pattern is achieved across the target area of the skin 714. The monitoring system 900 may use a computer 902, a mouse 904, and a charge coupled device (“CCD”) camera 906. In particular, the computer 902 receives the positional information about the system 700 from the CCD camera 906. The computer then updates the control module 702 based on this positional information as to the current position of the system 700. The control module 702 utilizes this information to cause the system 700 to create the appropriate damage pattern on the skin 714 within the target area. In addition, the monitoring system can utilize additional motion detecting devices, including, wheels or any other motion sensor.

The shape of the individual exposure areas 716 and the relative pattern represented by all of the individual exposure areas 716 may vary. The individual exposure areas 716 can have a circular, elliptical, rectangular, linear or irregular shape. The average distance between individual regions of unexposed skin surface may be in the range between 10 to 2000 μm , and preferably in the range of 100 to 500 μm . The macroscopic pattern of the individual exposure areas 716 may be a field of uniformly distributed individual exposure areas 716 with constant spacing throughout the target area, randomly distributed individual exposure areas 716 within the target area, and/or regularly distributed individual exposure areas 716 with constant average

spacing with randomly shifted location. In particular, having regularly distributed individual exposure areas 716 with constant average spacing with randomly shifted location may be useful to minimize undesirable effects, which may occur during multiple treatments. Such multiple treatments are utilized to cover the entire area as
5 homogeneously as possible by the individual exposure areas 716 during the course of multiple treatments. However, uniformly distributed individual exposure areas 716 with constant spacing throughout the target area may create unwanted spatial distributions similar to moiré patterns, resulting in spatial interference macroscopic patterns generated with a distance in between the areas of exposure which have a
10 significant spatial period. In order to minimize the occurrence of moiré patterns, a randomized shift within the range of 10 to 50% of the average distance between individual exposure areas 716 during a single scan may be utilized.

The treatment can be performed in by a single treatment covering the skin surface with a specific surface damage pattern, or by multiple treatments either
15 performed at the same visit or during different treatment visits. Individual or multiple exposures can be used to achieve the appropriate thermal damage in particular individual exposure areas 716.

Fractional resurfacing may cause portions of the epidermis to be thermally damaged or ablated, thereby reducing the efficacy of the barrier function of
20 the epidermis and in particular decreasing the stratum corneum. This facilitates the delivery of drugs or specific substances to the dermis and epidermis which can either enhance the effects of the treatment, or decrease the side effects caused by partial damage of the epidermis and/or dermis. Groups of drugs and substances, which may enhance the efficacy of skin remodeling include growth factors, collagen byproducts,
25 collagen precursors, hyaluronic acid, vitamins, antioxidants, amino acids and supplemental minerals among others. Groups of drugs and substances, which may decrease side effects, can be steroidal anti-inflammatory drugs, non-steroidal anti-inflammatory drugs, antioxidants, antibiotics, antiviral drugs, antiyeast drugs and antifungal drugs.

30 In an exemplary embodiment of the present invention, the vitamins that are used may be vitamin C and/or vitamin E. The supplemental minerals used are copper and zinc. The antioxidants can be vitamin C and/or vitamin E.

In a clinical observation, enhanced wound healing was observed for fractional resurfacing as compared to conventional resurfacing. The forearm skin of a

white, male Caucasian was exposed to pulsed CO₂ laser radiation with identical settings of the illuminating laser beam with a beam diameter of approximately 3 mm, a Coherent Ultra Pulse Laser, CPG handpiece, at approximately 300mJ/pulse. One area was exposed to the laser beam without benefit of a mask while another area was partially shielded by a cooled mask. More pronounced erythema was evident at the conventionally resurfaced test site as compared to the fractionally resurfaced test site.

The fill factor of the target area may be monitored by sensing the electrical impedance of the skin from a location on the skin within the target area to a remote location on the skin outside of the target area during or after treatment. An indicator capable of staining the defects in the stratum corneum (for example, trypan glue) or transdermal waterloss are effective indicators of the fill factor of the target area.

The foregoing merely illustrates the principles of the invention. Various modifications and alterations to the described embodiments will be apparent to those skilled in the art in view of the teachings herein. It will thus be appreciated that those skilled in the art will be able to devise numerous techniques which, although not explicitly described herein, embody the principles of the invention and are thus within the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An apparatus, comprising:
at least one member configured to mask at least one portion of a target area of skin from an electromagnetic radiation provided by an electromagnetic radiation source, wherein at least one member is configured such that a particular amount of the electromagnetic radiation that impacts the at least one member is reflected in a direction of the electromagnetic radiation source.
2. The apparatus of claim 1, wherein the target area is a predetermined area of the skin.
3. The apparatus of claim 1, wherein each of the at least one shielding member is configured to reflect the impacted electromagnetic radiation away from the apparatus.
4. The apparatus of claim 1, wherein each of the at least one shielding member is configured to absorb a minimal amount of electromagnetic radiation.
5. The apparatus of claim 1, wherein the electromagnetic radiation is optical radiation.
6. The apparatus of claim 1, wherein the electromagnetic radiation source is an ablative laser.
7. The apparatus of claim 1, wherein the electromagnetic radiation source is generated by a carbon dioxide laser.
8. The filtering apparatus of claim 1, wherein the electromagnetic radiation source is an Er:YAG laser.
9. The apparatus of claim 1, wherein the at least one shielding member masks at least 0.1% of the target area from the electromagnetic radiation.
10. The apparatus of claim 1, wherein the at least one member masks at most 90% of the target area from the electromagnetic radiation.
11. The apparatus of claim 1, wherein the at least one member masks the at least one portion of the target area such that the electromagnetic radiation is prevented

from affecting the at least one portion of the target area.

12. The apparatus of claim 1, wherein the at least one member is at least 50 μm in width and at most 300 μm .

13. The apparatus of claim 1, wherein the at least one member is configured to
5 define at least one aperture.

14. The apparatus of claim 13, wherein the at least one aperture has a width of at least 50 μm and at most 1000 μm .

15. The apparatus of claim 1, wherein the at least one member is cooled.

16. The apparatus of claim 1, wherein the at least one member is adapted to be
10 cooled to at least 37°C and at most negative 20°C .

17. The apparatus of claim 1, wherein the at least one member includes at least one channel extending therethrough.

18. The apparatus of claim 17, wherein the at least one channel is configured to facilitate a cooling agent.

15 19. A method for treating dermatological conditions, comprising:
controlling an electromagnetic radiation source to generate an electromagnetic radiation;
causing the electromagnetic radiation to be applied to a target area of skin; and
masking at least one portion of the target area of the skin from the
20 electromagnetic radiation.

20. The method of claim 19, wherein the masking step is performed using a mask which includes at least one member.

21. The method of claim 20, wherein the at least one shielding member masks at least 0.1% of the target area from the electromagnetic radiation.

25 22. The method of claim 20, wherein the at least one member masks at most 90% of the target area from the electromagnetic radiation.

23. The method of claim 20, wherein the at least one member masks the at least

one portion of the target area such that the electromagnetic radiation is prevented from affecting the at least one portion of the target area.

24. The method of claim 20, wherein the at least one member masks the at least one portion of the target area such that the electromagnetic radiation has an affect on
5 the at least one portion than an affect to other portions of the target area.

25. The method of claim 20, wherein the at least one member is at least 50 μm in width and at most 300 μm .

26. The method of claim 20, wherein the at least one member is configured to define at least one aperture.

10 27. The method of claim 26, wherein the at least one aperture has a width of at least 50 μm and at most 1000 μm .

28. The method of claim 20, wherein the at least one member is cooled.

29. The method of claim 20, wherein the at least one member is adapted to be cooled to at least 37°C and at most negative 20°C .

15 30. The method of claim 20, wherein the at least one member includes at least one channel extending therethrough.

31. The method of claim 30, wherein the at least one channel is configured to facilitate a cooling agent.

20 32. The method of claim 19, wherein the mask is configured to reflect a predetermined amount of the electromagnetic radiation in a direction of the electromagnetic radiation source.

33. The method of claim 19, wherein the mask is configured to reflect the electromagnetic radiation away from the electromagnetic radiation source.

25 34. The method of claim 19, wherein the mask is configured to diffuse the electromagnetic radiation.

35. The method of claim 19, wherien the electromagnetic radiation has a particular wavelength.

36. The method of claim 35, wherein a surface of the mask has a microstructure having a periodicity approximately in the range of the particular wavelength.
37. The method of claim 19, wherein the mask is configured to absorb a predetermined amount of the electromagnetic radiation.
- 5 38. The method of claim 19, wherein the electromagnetic radiation source is an ablative laser.
39. The method of claim 19, wherein the electromagnetic radiation source is a carbon dioxide laser.
40. The method of claim 19, wherein the electromagnetic radiation source is a
10 Er:YAG laser.
41. The method of claim 19, further comprising the steps of:
controlling a further electromagnetic radiation source to generate a further electromagnetic radiation; and
applying the further electromagnetic radiation to the target area of the skin.
- 15 42. The method of claim 41, wherein the further electromagnetic radiation source is substantially the same as the electromagnetic radiation source.
43. The method of claim 41, wherein the further electromagnetic radiation source is different than the electromagnetic radiation source.
44. The method of claim 41, wherein the further electromagnetic radiation source
20 is one of a Q-switched ruby laser, a Nd:YAG laser, a KTP laser and an Alexandrite laser.
45. The method of claim 19, further comprising the step of introducing a substance to the target area, wherein the substance is one of growth factors, collagen byproducts, collagen precursors, hyaluronic acid, vitamins, antioxidants, amino acids
25 and supplemental minerals.
46. An apparatus for treating dermatological conditions, comprising:
a delivery module configured to direct an electromagnetic radiation generated by an electromagnetic radiation source to a target area of skin; and

a mask including at least one member configured to mask at least one portion of the target area of the skin from the electromagnetic radiation.

47. The apparatus of claim 46, wherein the at least one member is configured to reflect a predetermined amount of the electromagnetic radiation in the direction of the
5 electromagnetic radiation source.

48. The apparatus of claim 46, wherein each of the at least one member is configured to reflect the electromagnetic radiation away from the electromagnetic radiation source.

49. The apparatus of claim 46, wherein each of the at least one member is
10 configured to diffuse the electromagnetic radiation.

50. The apparatus of claim 46, wherein the electromagnetic radiation has a particular wavelength.

51. The apparatus of claim 50, wherein each of the at least one member includes a microstructure having a periodicity in the range of the particular wavelength.

15 52. The apparatus of claim 46, wherein each of the at least one member is configured to absorb a minimal amount of the electromagnetic radiation.

53. The apparatus of claim 46, wherein the electromagnetic radiation source is an ablative laser.

54. The apparatus of claim 46, wherein the electromagnetic radiation source is a
20 carbon dioxide laser.

55. The apparatus of claim 46, wherein the electromagnetic radiation source is a Er:YAG laser.

56. The apparatus of claim 46, wherein the at least one shielding member masks at least 0.1% of the target area from the electromagnetic radiation.

25 57. The apparatus of claim 46, wherein the at least one member masks at most 90% of the target area from the electromagnetic radiation.

58. The apparatus of claim 46, wherein the at least one member masks the at least

one portion of the target area such that the electromagnetic radiation is prevented from affecting the at least one portion of the target area.

59. The apparatus of claim 46, wherein the at least one member masks the at least one portion of the target area such that the electromagnetic radiation is prevented from affecting the at least one portion of the target area.

60. The apparatus of claim 46, further comprising a case having an aperture formed in a sidewall of the case, wherein the case contains the electromagnetic radiation source and the delivery module, and wherein the at least one member is in registration with the aperture.

61. The apparatus of claim 46, wherein the delivery module includes a beam collimator.

62. The apparatus of claim 46, wherein the delivery module includes optical components.

63. An apparatus for treating dermatological conditions, comprising:
a delivery module configured to direct electromagnetic radiation generated by an electromagnetic radiation source to a predetermined area within a target area of skin, wherein the predetermined area is located in a location relative to the delivery module, and wherein the electromagnetic radiation is adapted to cause thermal damage to epidermal tissue and dermal tissue of the predetermined area within the target area of the skin; and

a translator capable of moving the delivery module, such that the delivery module targets a plurality of spatially separated individual exposure areas of the predetermined area.

64. The apparatus of claim 63, wherein the electromagnetic radiation source is an ablative laser.

65. The apparatus of claim 63, wherein the electromagnetic radiation source is one of a diode laser, a fiber laser, a solid state laser and a gas laser.

66. The apparatus of claim 63, further comprising a case having an aperture formed in a sidewall of the case, wherein the case contains the electromagnetic

radiation source, the delivery module and the translator.

67. The apparatus of claim 66, further comprising a transparent plate in registration with the aperture, wherein the transparent plate seals the case.

68. The apparatus of claim 67, wherein the electromagnetic radiation has a particular wavelength.

69. The apparatus of claim 68, wherein the transparent plate absorbs a predetermined amount of the electromagnetic radiation at the particular wavelength.

70. The apparatus of claim 67, wherein the transparent plate is cooled to provide an asthetic affect to the target area of the skin.

71. The apparatus of claim 67, wherein the transparent plate is configured to be cooled to at least 37°C and at most negative 20°C.

72. The apparatus of claim 63, wherein the delivery module includes a beam collimator.

73. The apparatus of claim 63, wherein the delivery module includes optical components.

74. The apparatus of claim 63, wherein the dermal tissue of the skin of the plurality of spatially separated individual exposure areas is damaged down to a predetermined depth thereof.

75. The apparatus of claim 63, wherein the plurality of spatially separated individual exposure areas cover at least five percent of the target area and at most sixty percent of the target area.

76. The apparatus of claim 63, wherein an average distance between each of the plurality of spatially separated individual exposure areas is at least 10 μm and at most 2000 μm .

77. The apparatus of claim 63, wherein each of the plurality of spatially separated individual exposure areas have a diameter of approximately 0.1 mm.

78. The apparatus of claim 63, wherein each of the plurality of spatially separated

individual exposure areas have a lateral diameter of a smallest dimension of at least 1 μm and at most 500 μm .

79. The apparatus of claim 63, further comprising an optically transparent plate disposed between delivery module and the target area of the skin.

5 80. The apparatus of claim 79, wherein the optically transparent plate is cooled.

81. The apparatus of claim 79, wherein the optically transparent plate cooled to at least 37°C and at most negative 20°C .

82. The apparatus of claim 63, wherein a first one of the plurality of spatially separated individual exposure areas is separated from a second one of the plurality of spatially separated individual exposure areas.
10

83. The apparatus of claim 82, wherein the first one of the plurality of spatially separated individual exposure areas is separated from the second one of the plurality of spatially separated individual exposure areas by non-irradiated skin section.

84. The apparatus of claim 63, wherein a first one of the plurality of spatially separated individual exposure areas is exposed to electromagnetic radiation associated with a first set of parameters and a second one of the plurality of spatially separated individual exposure areas is exposed to electromagnetic radiation associated with a second set of parameters.
15

85. The apparatus of claim 63, wherein at least two of the individual exposure areas are separated from one another by an unaffected area.
20

86. The apparatus of claim 85, wherein the at least two of the individual exposure areas are separated from one another by at least approximately 125 μm .

87. The apparatus of claim 85, wherein the at least two of the individual exposure areas are separated from one another by at most approximately 500 μm .

25 88. The apparatus of claim 63, wherein one of at least one hundred of the individual exposure areas within an area of a square centimeter is separated from another one of the at least one hundred of the individual exposure areas by an unaffected area.

89. The apparatus of claim 63, wherein one of at least one thousand of the individual exposure areas within an area of a square centimeter is separated from another one of the at least one thousand of the individual exposure areas by an unaffected area.

- 5 90. A method for treating dermatological conditions, comprising the steps of:
- (a) controlling an electromagnetic radiation source to generate first and second electromagnetic radiation;
 - (b) causing a first electromagnetic radiation to be applied to a first individual exposure area of a plurality of spatially separated individual exposure areas of a target
 - 10 area of skin, wherein epidermal tissue and dermal tissue of the first individual exposure area are thermally damaged; and
 - (c) causing a second electromagnetic radiation to be applied to a second individual exposure area of a plurality of spatially separated individual exposure areas of the target area of the skin, wherein epidermal tissue and dermal tissue of the second
 - 15 individual exposure area are thermally damaged, wherein the first electromagnetic radiation is one of the same as and different from the second electromagnetic radiation, and wherein the first and second individual exposure areas are separated from one another by an unaffected area.

20 91. The method of claim 90, wherein the target area has a surface area of approximately 1 cm².

92. The method of claim 90, wherein the electromagnetic radiation source is an ablative laser.

93. The method of claim 90, wherein the electromagnetic radiation source is one of a diode laser, a fiber laser, a solid state laser and a gas laser.

25 94. The method of claim 90, wherein the dermal tissue of the skin of the plurality of spatially separated individual exposure areas is damaged down to a predetermined depth thereof.

95. The method of claim 90, wherein the plurality of spatially separated individual exposure areas cover at least twenty percent of the target area and at most fourty

30 percent of the target area.

96. The method of claim 90, wherein an average distance between each of the plurality of spatially separated individual exposure areas is at least approximately 10 μm and at most approximately 2000 μm .
97. The method of claim 90, wherein each of the plurality of spatially separated individual exposure areas have a diameter of approximately 0.1 mm.
98. The method of claim 90, wherein each of the plurality of spatially separated individual exposure areas have a lateral diameter of a smallest dimension of at least approximately 1 μm and at most approximately 500 μm .
99. The method of claim 90, further comprising the step of:
- (d) placing an optically transparent plate in registration with the target area.
100. The method of claim 99, wherein the optically transparent plate is cooled.
101. The method of claim 99, wherein the optically transparent plate cooled to at least approximately 37°C and at most approximately negative 20°C .
102. The method of claim 90, wherein the first individual exposure area is separated from a second individual exposure area.
103. The method of claim 90, wherein the first individual exposure area is separated from the second individual exposure area by non-irradiated skin.
104. The method of claim 90, wherein the first electromagnetic radiation is associated with a first set of parameters, and wherein the second electromagnetic radiation is associated with a second set of parameters.
105. The method of claim 90, wherein at least two of the individual exposure areas are separated from one another by an unaffected area.
106. The method of claim 105, wherein the at least two of the individual exposure areas are separated from one another by at least approximately 125 μm .
107. The method of claim 105, wherein the at least two of the individual exposure areas are separated from one another by at most approximately 500 μm .

108. The method of claim 90, wherein one of at least one hundred of the individual exposure areas within an area of a square centimeter is separated from another one of the at least one hundred of the individual exposure areas by an unaffected area.

109. The method of claim 90, wherein one of at least one thousand of the individual exposure areas within an area of a square centimeter is separated from another one of the at least one thousand of the individual exposure areas by an unaffected area.

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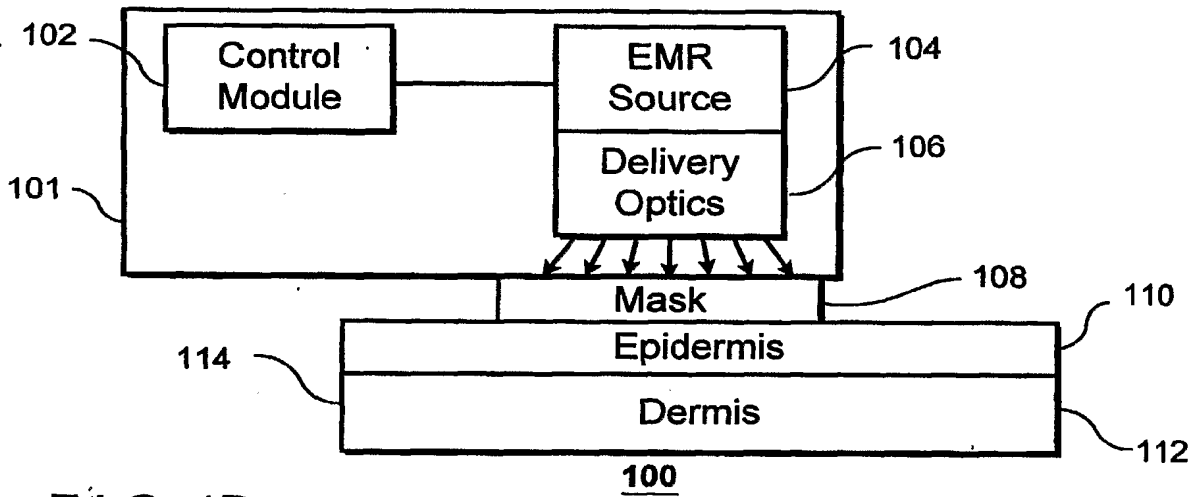
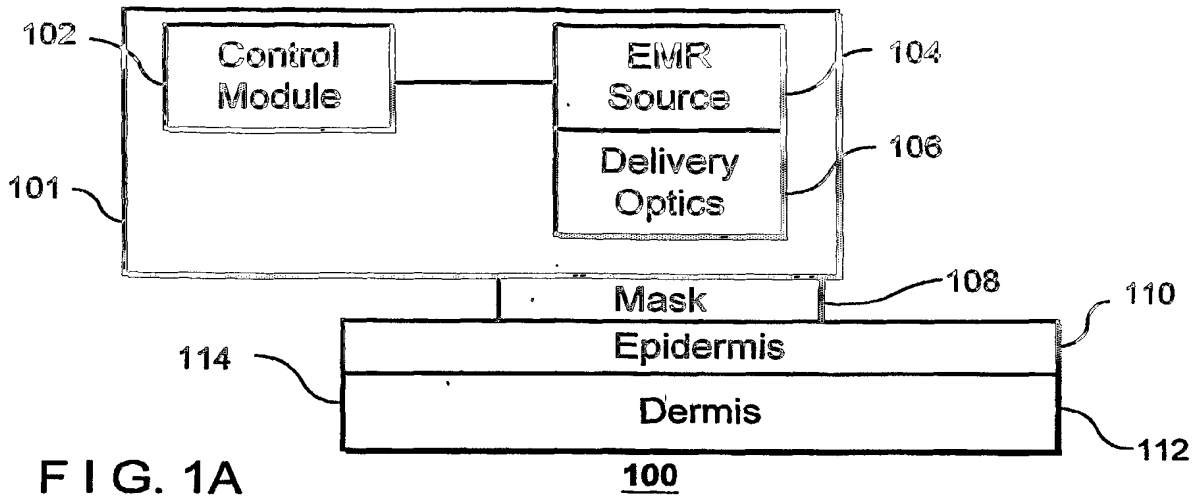


FIG. 1B

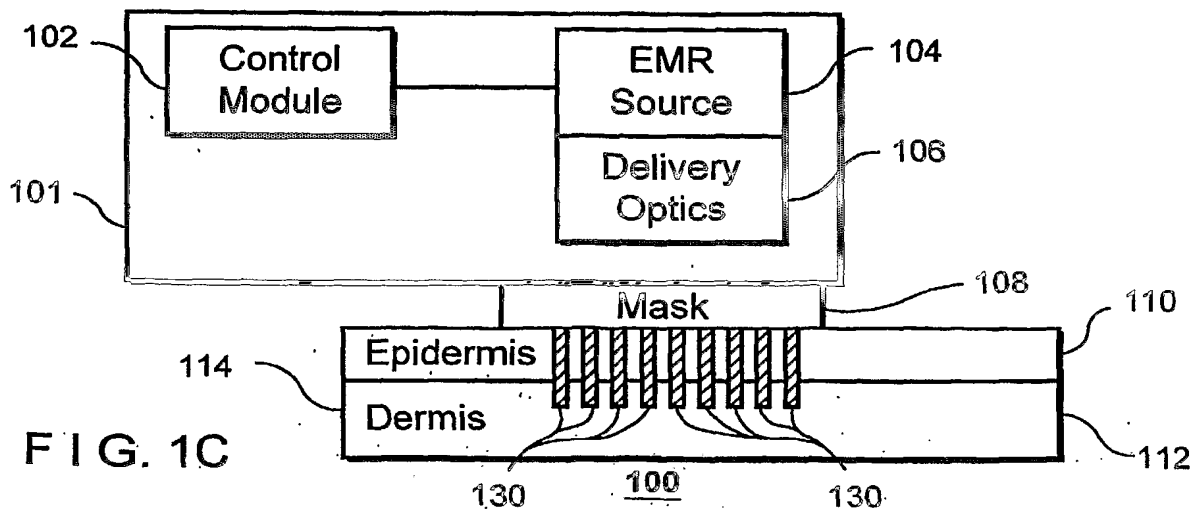


FIG. 1C

2/5

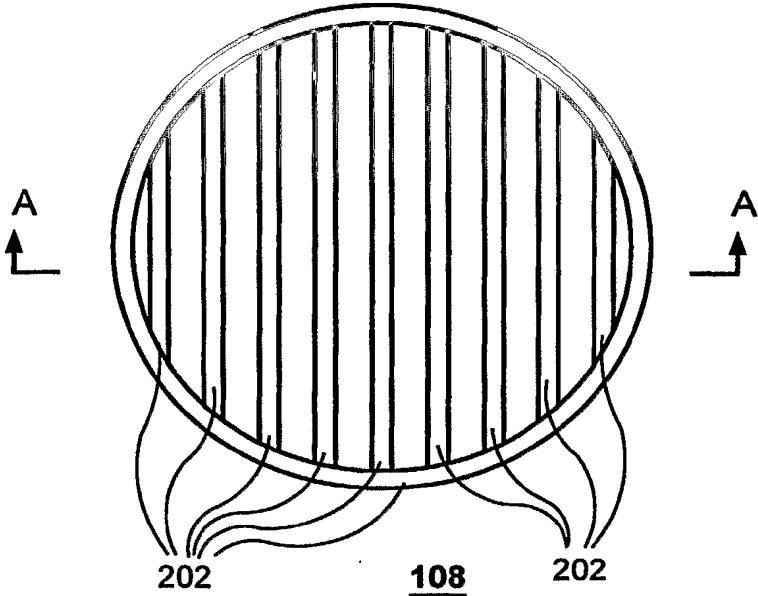


FIG. 2

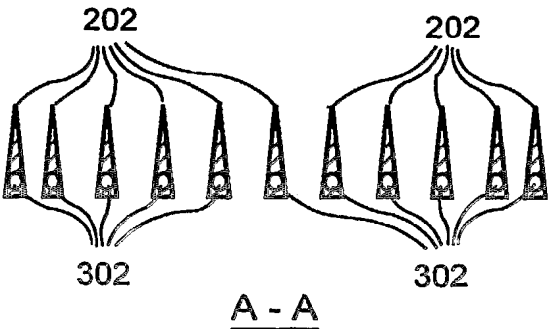


FIG. 3

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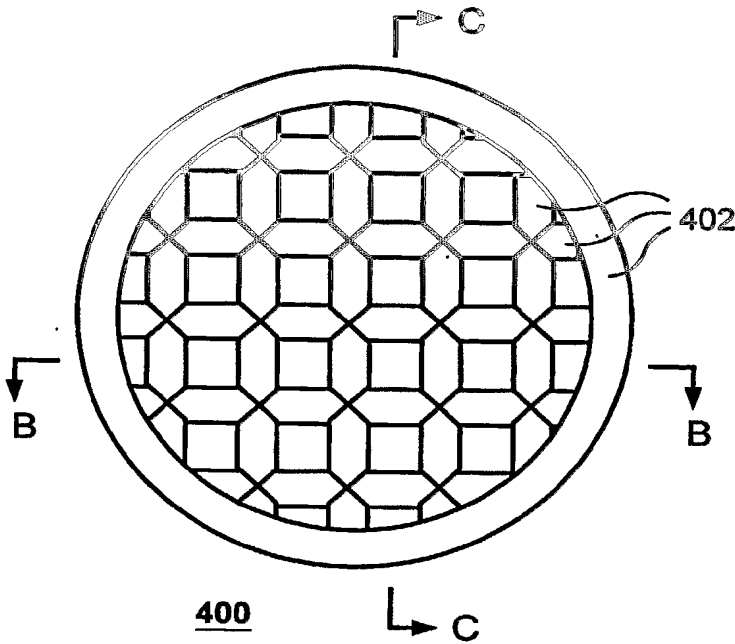


FIG. 4

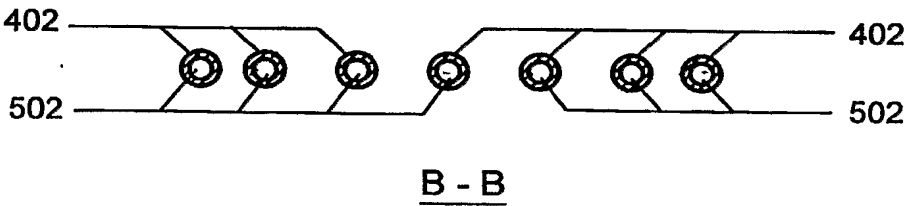


FIG. 5

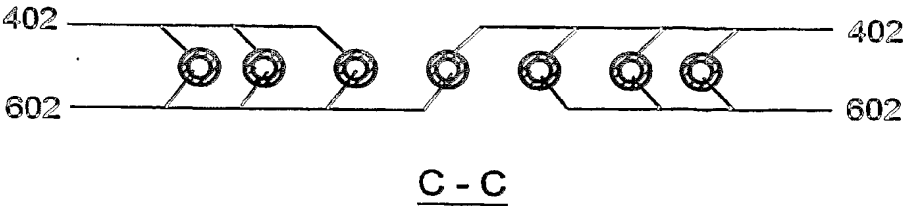


FIG. 6

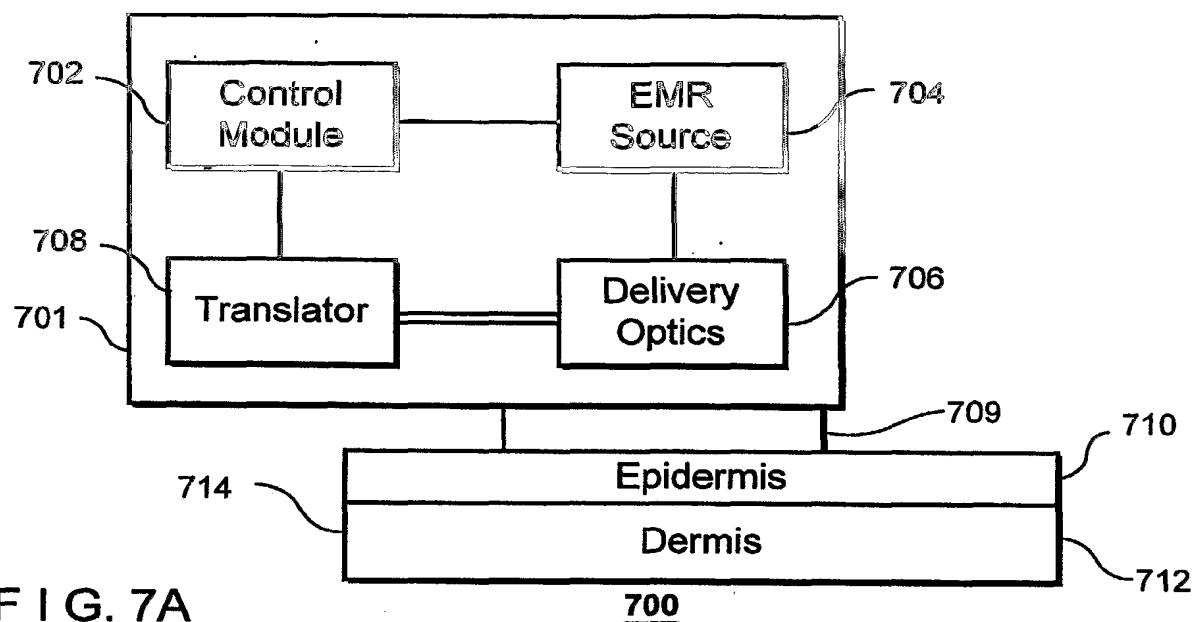


FIG. 7A

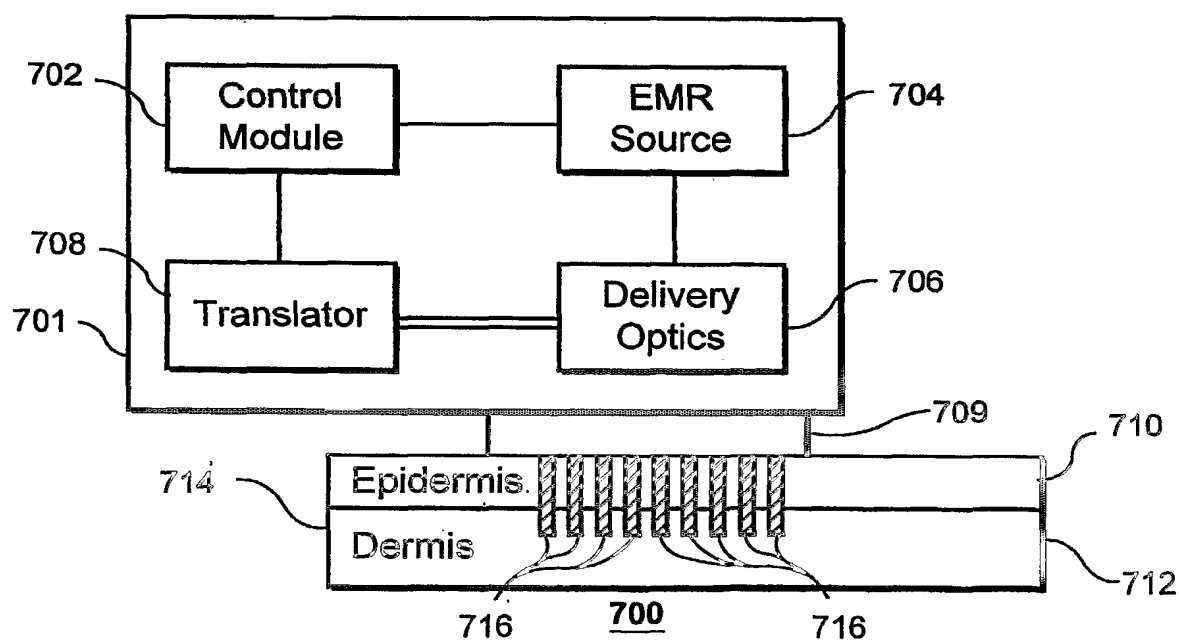


FIG. 7B

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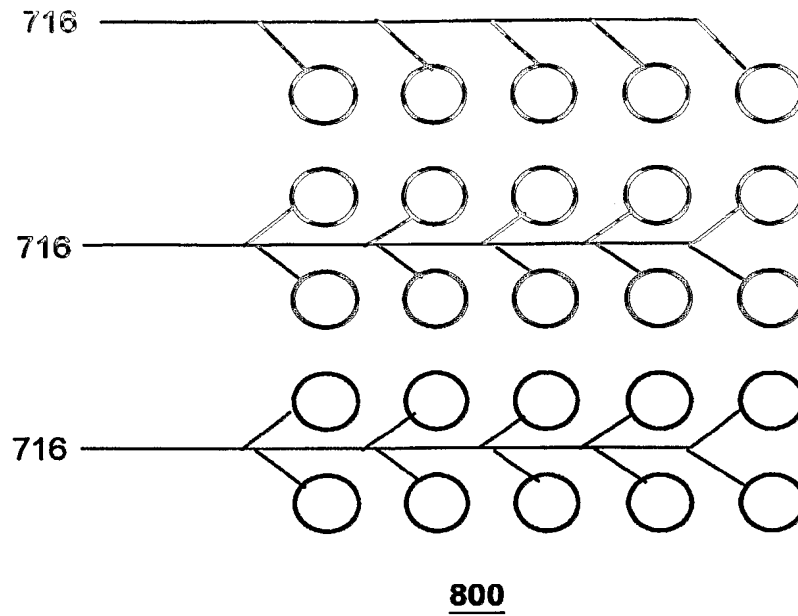


FIG. 8

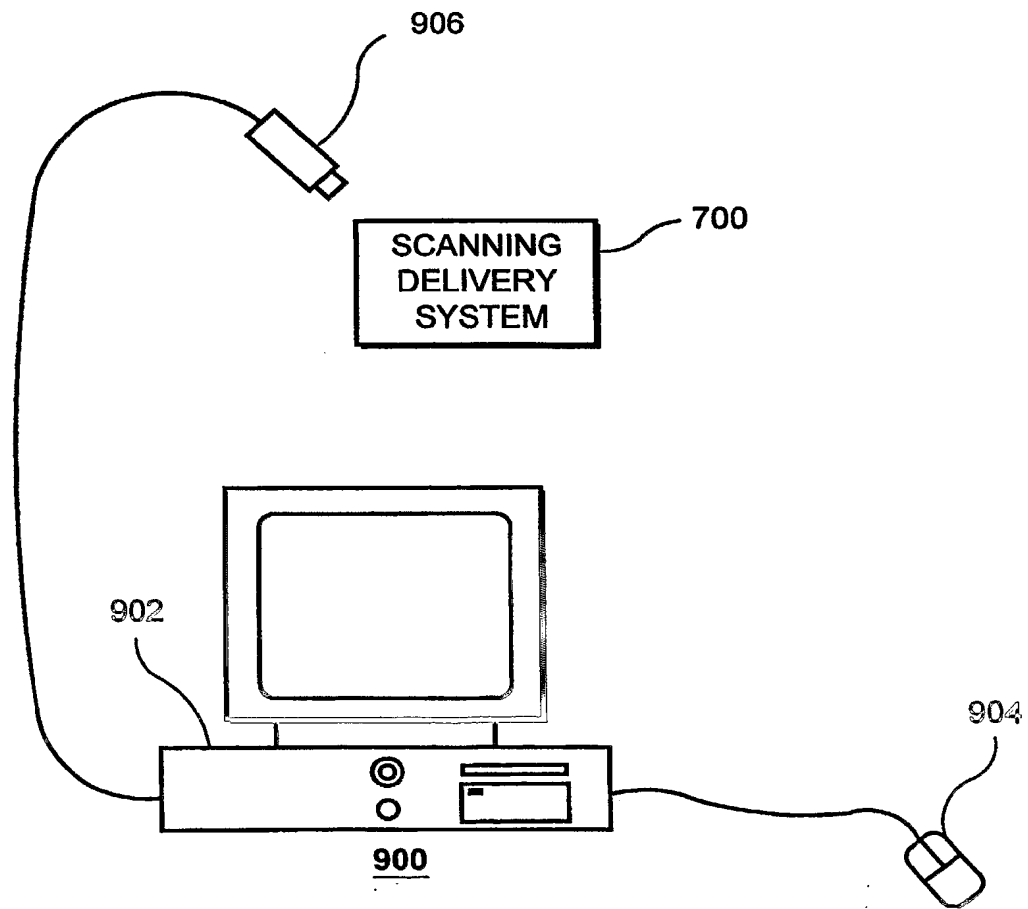


FIG. 9